Annual Transplant Surgeon Designee Symposium

Virtua Center for Organ Transplantation

November 18, 2021

Introduction and Overview of Transplantation

Manasa Ujire, MD

Disclosure

End-Stage Renal Disease (ESRD) in the United States

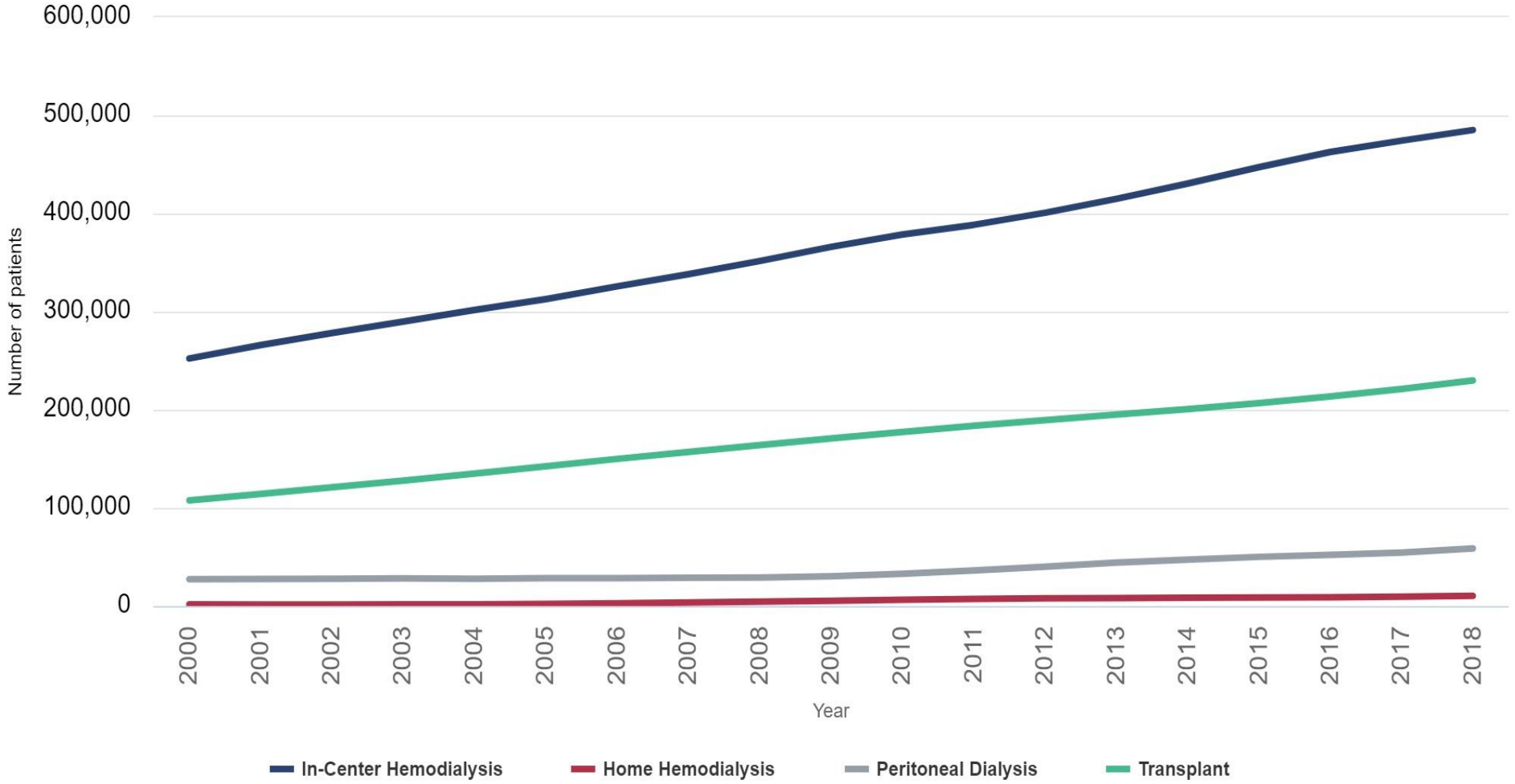
- Prior to 1970, treatment options for patients with ESRD were limited due to the small number of dialysis centers available
- In 1972, the passage of legislation for Medicare to cover the cost of maintenance dialysis expanded options
- Currently, there are over 700,000 patients living with ESRD in the United States
- Although there have been several advances in dialysis over the past 5 decades, patients who are on maintenance dialysis continue to have a poor state of health

Complications of ESRD

- Progressive cardiovascular disease
- Peripheral and autonomic neuropathy
- Bone disease
- Peripheral vascular disease
- Symptoms of fatigue and malaise due to anemia
- Sexual dysfunction
- Physical, emotional, and financial dependency on others
- Poor vocational rehabilitation availability

ESRD :Prevalence

Figure 1.6 Number of prevalent ESRD patients, by modality, 2000-2018



Data Source: 2020 United States Renal Data System Annual Data Report

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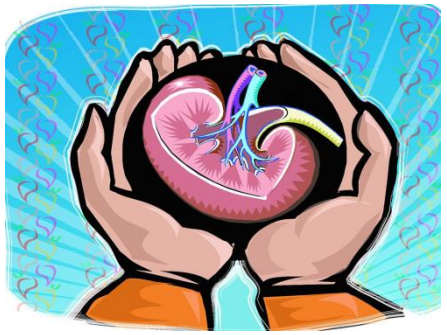
Options for Management of End-Stage Renal Disease

- Renal Replacement Therapy (RRT)
  - Dialysis
    - Hemodialysis (home or in-center), Peritoneal Dialysis (home)
  - Kidney Transplantation
    - Improves quality of life (vs dialysis)
    - Offers a survival advantage over dialysis
- Conservative Management/Supportive Care
  - Refers to non-RRT treatment

Organ Transplantation



- Early 1950s, birth of transplant immunology
- In 1954, the modern era of clinical transplant began with the first living donor kidney transplant between identical twin brothers
- Before 1970, transplant immunology and immunosuppressive therapy were in their infancy
- In 1972, passage of legislation for Medicare entitlement for kidney transplant recipients
- 1970s-2000s dramatic increase in options available for immunosuppressive (anti-rejection) therapy

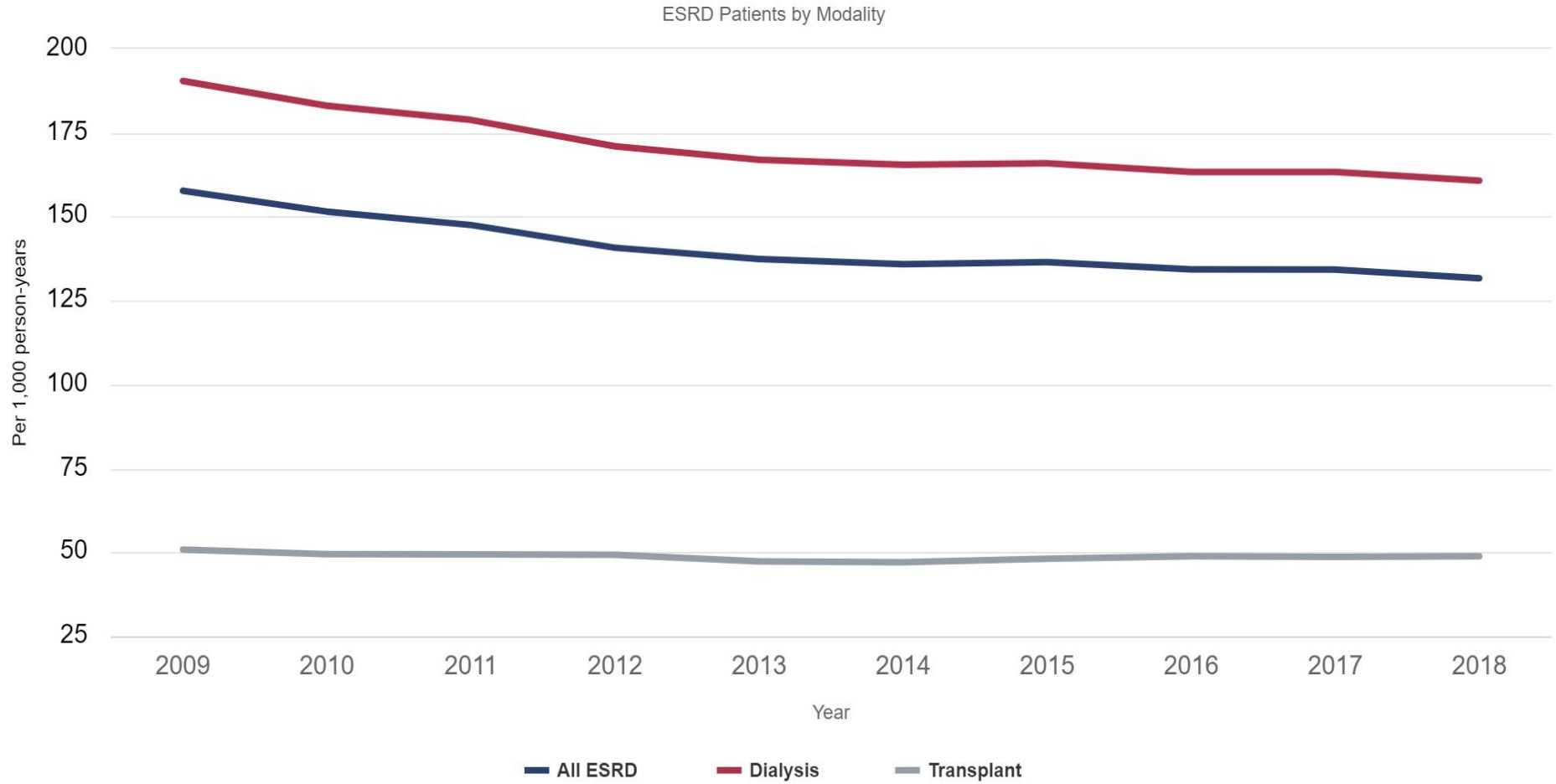
Goal of Kidney Transplantation

The goal of kidney transplantation in ESRD/advanced CKD is to allow

- freedom from dialysis
- improve quality of life
- increase long-term patient survival

Mortality: Dialysis Vs Kidney Transplant

Figure 5.1 Adjusted all-cause mortality for patients with prevalent ESRD, by treatment modality, 2009-2018



Data Source: 2020 United States Renal Data System Annual Data Report

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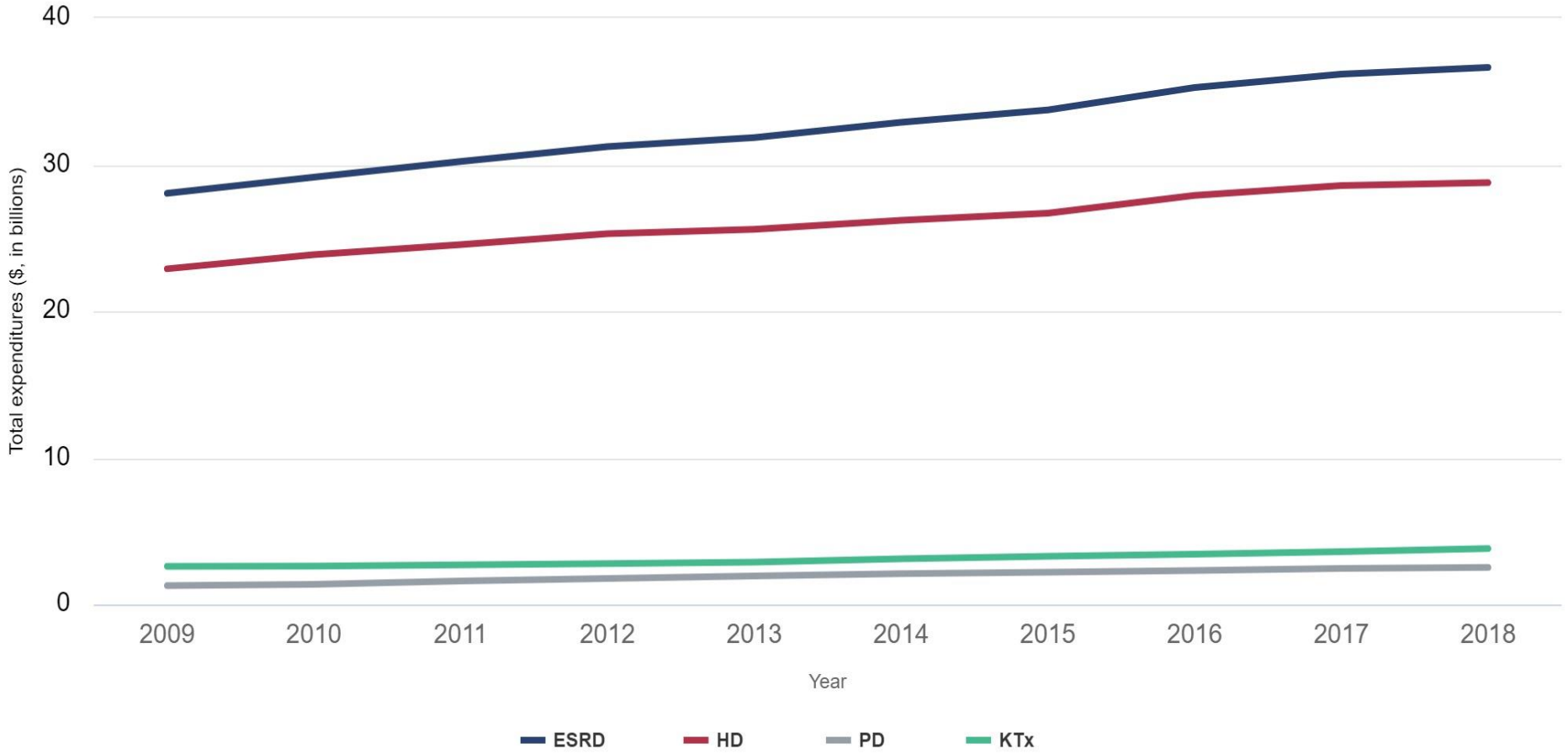
Cost :Dialysis Vs Kidney Transplant

Figure 9.8 Unadjusted total Medicare fee-for-service expenditures for beneficiaries with ESRD by treatment modality, 2009-2018



Data Source: 2020 United States Renal Data System Annual Data Report

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Kidney Transplant

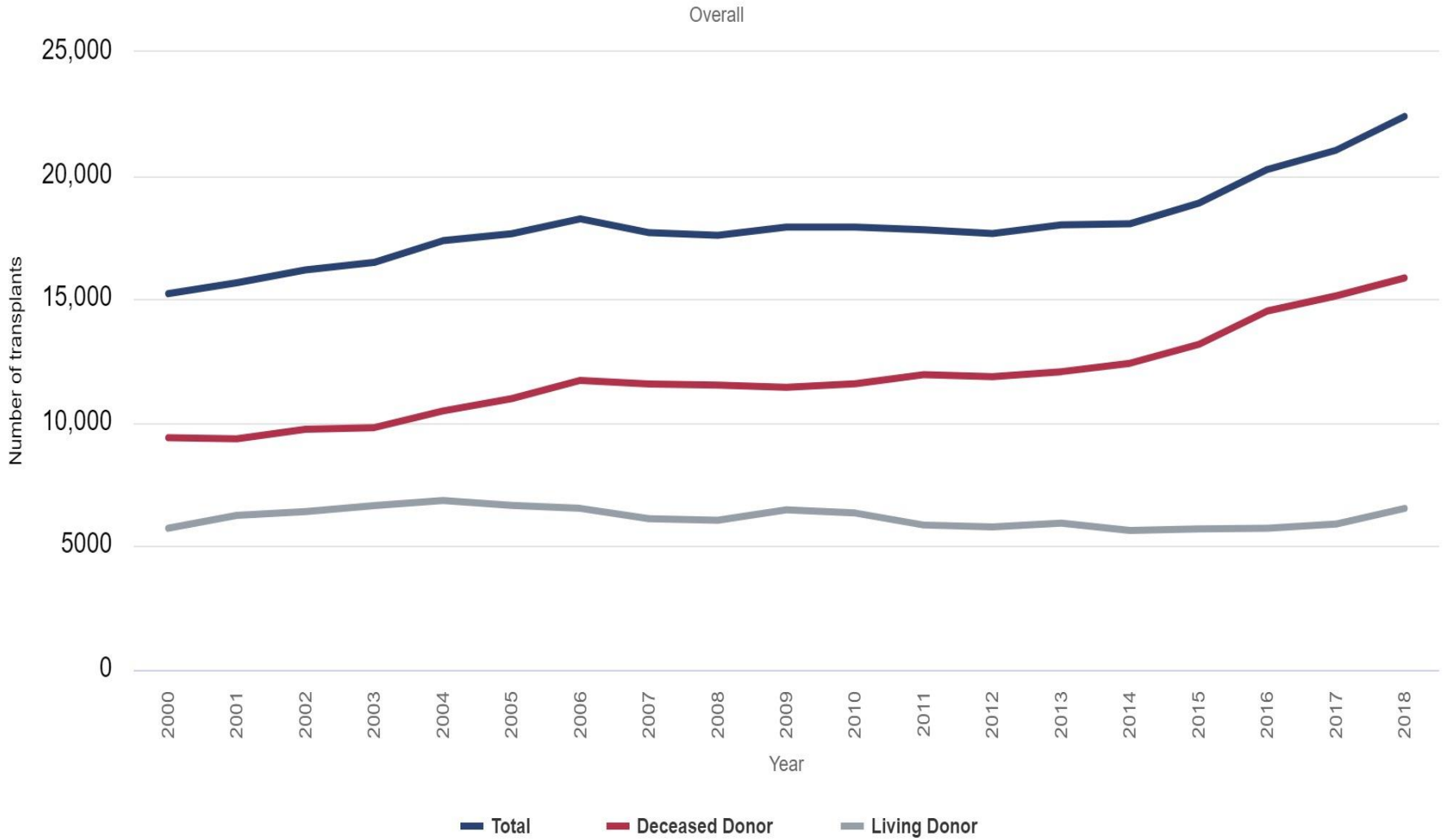
- Deceased Donor Kidney Transplant (DDRT)
  - Brain Dead Donor (BDD)
  - Donation After Cardiac Death (DCD)

- Living Donor Kidney Transplant (LDKT)
  - Living Related/ Living Unrelated
  - Paired Exchange

Donor categories

- Deceased Donor
  - Kidney Donor Profile Index (KDPI) > 85%
  - Identified Risk for acute viral transmission
  - Hepatitis C Ab + (NAT negative) ,-nonviremic
  - Hepatitis C NAT + viremic
  - Hepatitis B core Ab +,NAT negative ,-nonviremic
- Living Donor

Figure 6.9 Count and rate of kidney transplants in patients undergoing dialysis, 2000-2018



Data Source: 2020 United States Renal Data System Annual Data Report

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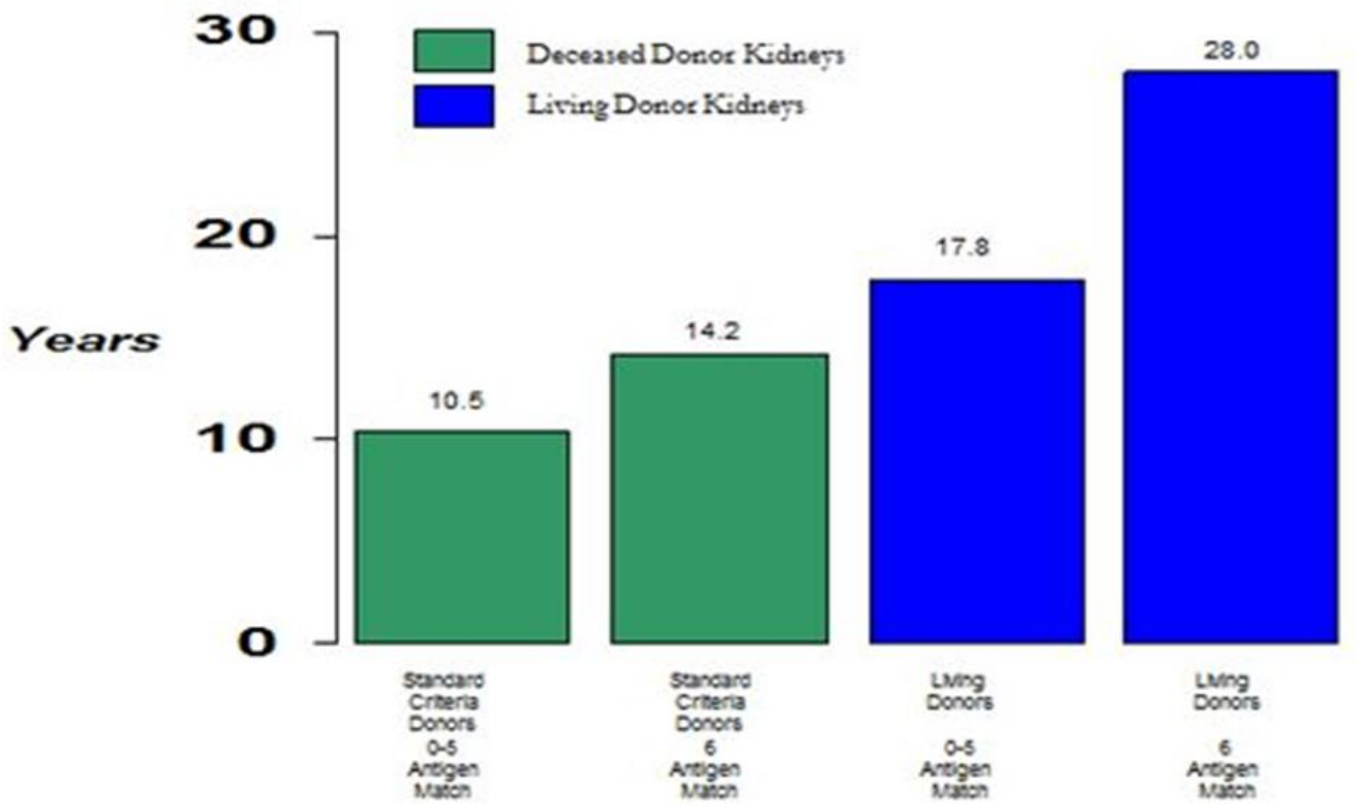
Why Living Donation

- Better quality organ
- Last longer
- Better kidney function
- Immediate
- Preemptive transplant
- Opportunity for desensitization
- Better preparedness

Living Donor Kidneys Last Longer

Well matched living donor kidneys last even longer



Graft half life. The point in time when exactly 50% of kidneys are still functioning

Source: ClinicalTransplants 2005

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Paired Exchange

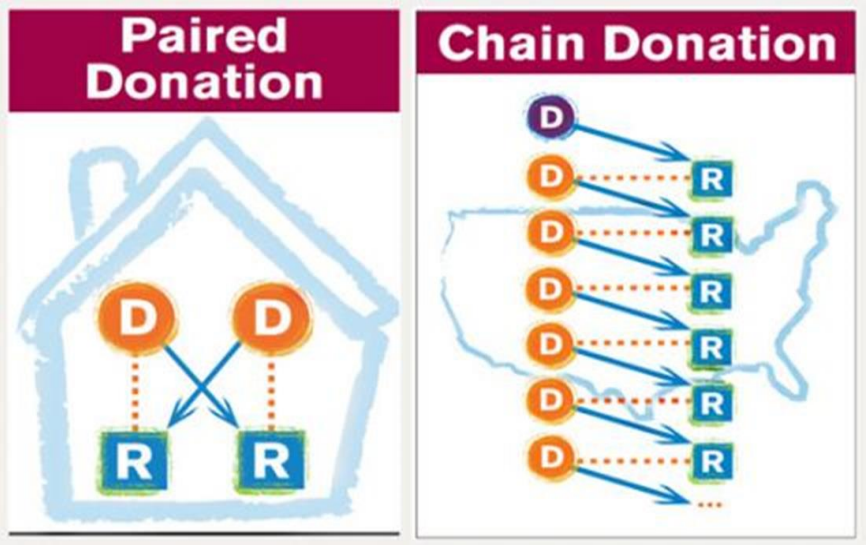
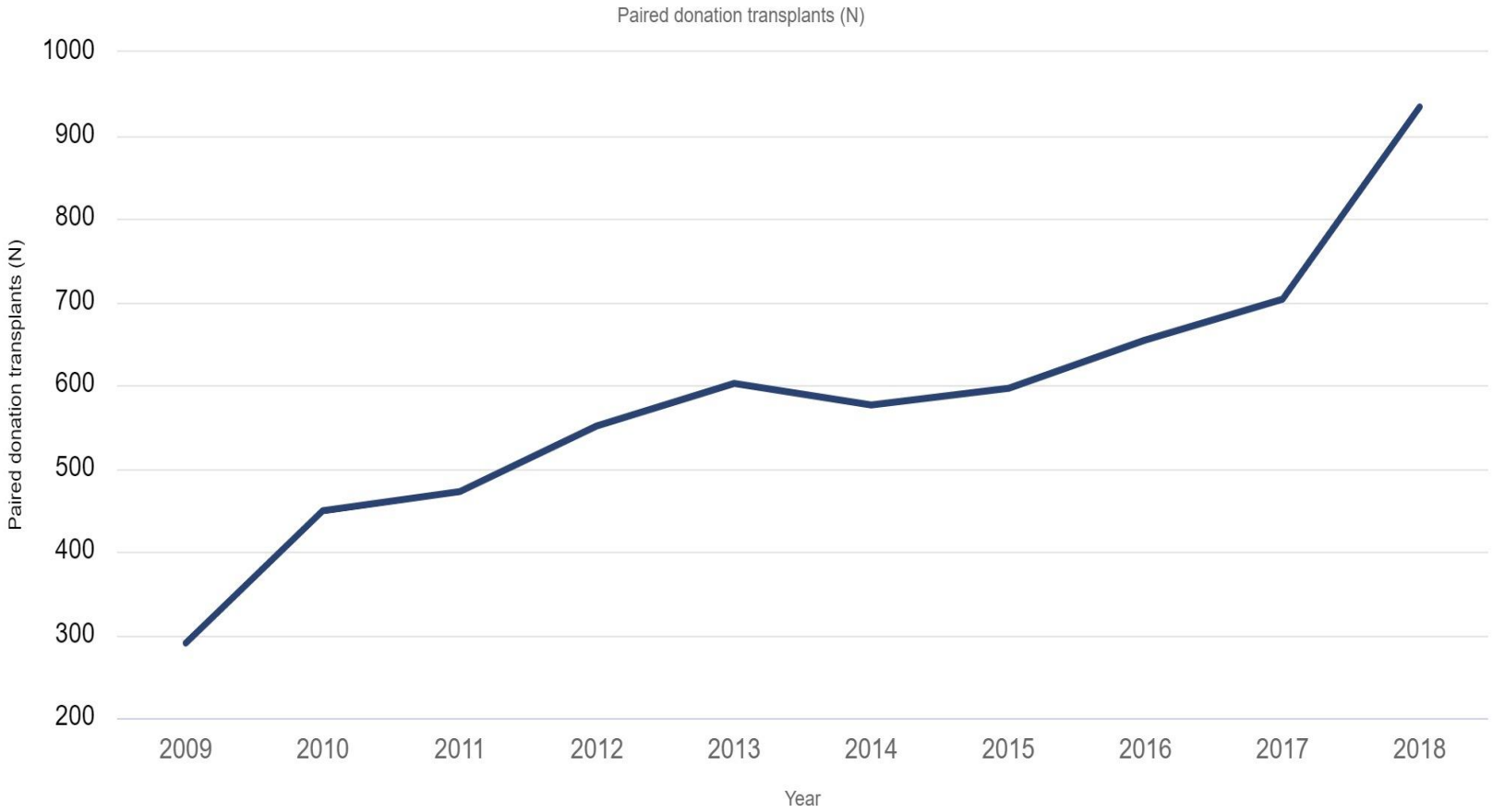


Figure 6.12 Number of paired donation transplants, percentage of transplants that were due to paired donation, and percentage of centers performing paired donation transplants, 2009-2018



Data Source: 2020 United States Renal Data System Annual Data Report

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The Deceased Donor Kidney Waitlist

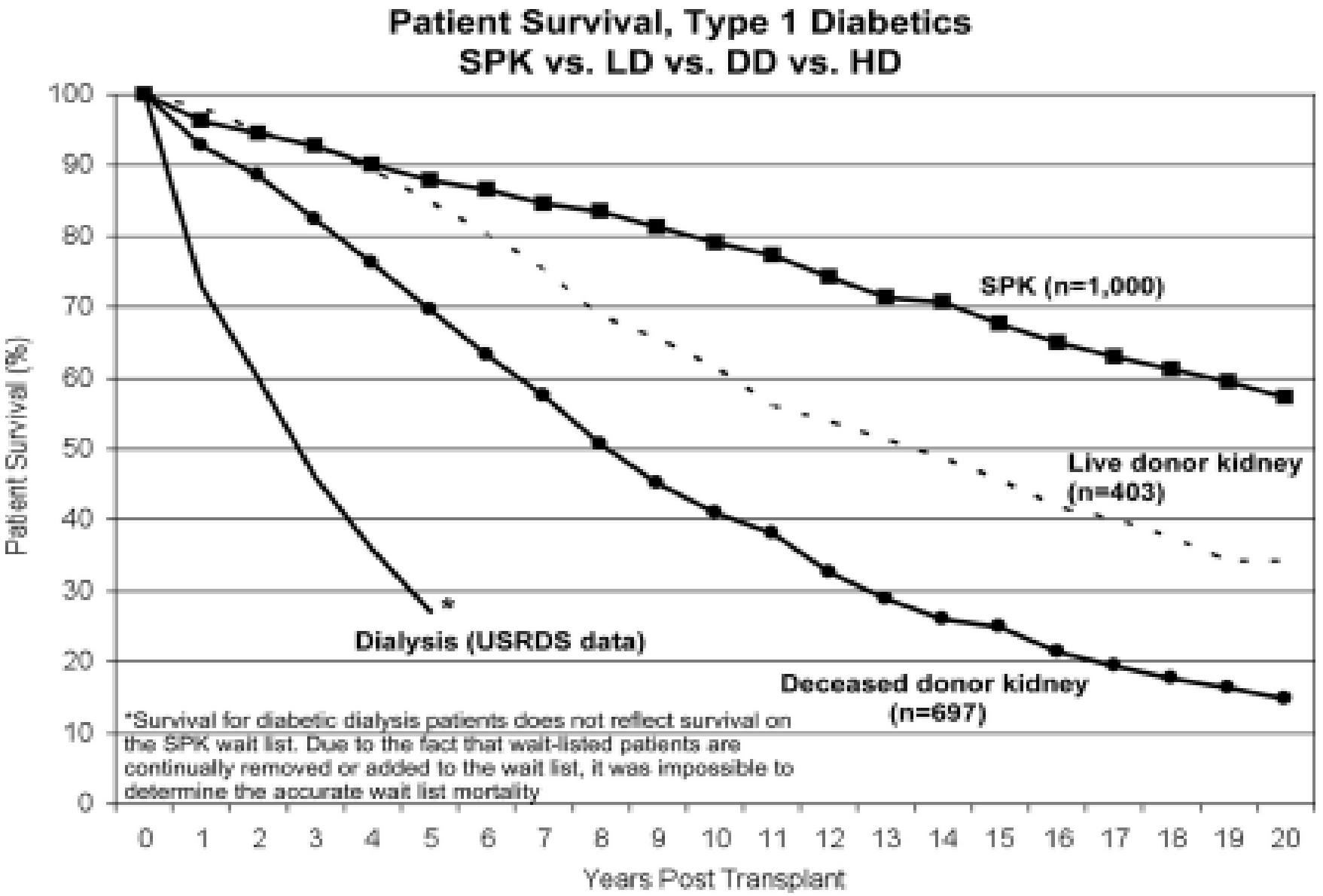
- For candidates ≥18 years old, the calculation of waiting time is based upon the earliest of the following:
  - The date that the candidate starts regularly administered dialysis as an end-stage renal disease (ESRD) patient
  - The registration date if the patient is pre-dialysis and the measured or estimated GFR is ≤20 mL/min

Pancreas Transplant

- Simultaneous kidney transplantation(SPK) in selected patients with diabetes and ESRD/advanced CKD, who will already be required to take immunosuppressive therapy for the kidney graft.

- Pancreas after kidney (PAK) and pancreas transplant alone (PTA) are performed less commonly.

- The goal of pancreas transplantation in diabetics is to allow insulin independence, improve quality of life, and reduce secondary complications.



Sollinger et al Annals of Surgery Oct 2009

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Kidney Allocation

- A national kidney allocation policy was established in the United States in 1987 for the purpose of the equitable and utilitarian distribution of deceased-donor kidneys.
- A revised national kidney allocation policy was implemented on Dec 2014 in order to increase the utilization of available kidneys and maximize the number of years that individual recipients may have a functioning allograft, taking into account donor quality (KDPI score), recipient estimated post-transplant survival (EPTS), and recipient sensitivity (cPRA)

- The national kidney allocation policy changed again in March 2021 to increase equity with broader distribution – more to come later today

Questions?

Evaluation of the Transplant Candidate- Inclusion/Exclusion Criteria

Anita Mehrotra, MD, FASN, FAST

Transplant Nephrologist

Virtua Our Lady of Lourdes Center for Organ Transplantation

Camden, NJ

Disclosure

Indications for Kidney Transplantation

- End Stage Renal Disease (ESRD) on renal replacement therapy (hemodialysis or peritoneal dialysis)
- Advanced renal failure – eGFR ≤ 20 mL/min
  - “Pre-emptive” kidney transplantation

Contraindications to Kidney Transplantation

(Varies among transplant centers/programs)

- Absolute Contraindications
  - Positive CDC (complement dependent cytotoxicity) crossmatch (risk increases with sensitizing events, like blood transfusions – should be avoided pre-transplant whenever possible!)
  - Untreated current infection
  - Chronic illness with life expectancy < 1 year
  - Active substance abuse
  - Lack of cognitive capacity to make informed decisions, understand the procedure, and sign the consent

Contraindications to Kidney Transplantation

(Varies among transplant centers/programs)

- Relative Contraindications
  - Cirrhosis of liver (may be eligible for combined liver/kidney tx)
  - HIV (unless on HAART with undetectable viral load, CD4 count > 200 and no AIDS-related complications) – refer to program with special expertise
  - Advanced COPD or pulmonary HTN
  - Severe or unrevascularized CAD or CHF with EF < 30% (may be considered for combined heart/kidney tx at a cardiac transplant center)
  - Active or recent malignancy, other than superficial skin cancers
    - Waiting time for clearance discussed on case-by-case basis

Contraindications to Kidney Transplantation

(Varies among transplant centers/programs)

- Relative Contraindications, cont.
  - Proven habitual medical noncompliance
  - Uncontrolled psychiatric condition
  - Active systemic lupus erythematosis or other immunologic disease
  - Obesity (BMI ≥ 40)
  - Severe PVD
  - Severe cerebrovascular disease
  - No insurance/limited coverage for immunosuppressive medications
  - Current active smoking

Indications for Pancreas Transplantation

- Simultaneous kidney-pancreas transplant (or pancreas after kidney transplant)
  - For patients with diabetes (ON INSULIN) or pancreas exocrine insufficiency and who otherwise meet criteria for kidney transplantation (ESRD on dialysis or eGFR ≤ 20 mL/min)
- Pancreas transplantation alone
  - Patients with diabetes (ON INSULIN) who do not have substantial renal disease are candidates for pancreas transplantation alone if they have a history of frequent, acute, severe metabolic complications (hypoglycemia, marked hyperglycemia, ketoacidosis); incapacitating clinical and emotional problems with exogenous insulin therapy; and consistent failure of insulin-based management to prevent acute complications.

Contraindications to Pancreas Transplantation (Varies among transplant centers/programs)

- Similar to the list of contraindications to kidney transplantation, but also may include a lower BMI cutoff that is center-specific

Evaluation Process

The evaluation process includes a comprehensive evaluation by the entire team including but not limited to:

1. Application of absolute contraindications
2. Medical history and physical
3. Psycho-social evaluation, including compliance history, drug and alcohol use
4. Dietary evaluation
5. Patient and family education
6. Insurance review by the Social Worker and/or Finance Coordinator
7. Required testing
8. Immunological evaluation
    a. Blood typing (ABO group determination and Rh
    b. HLA typing
    c. Antibody screening
    d. Cross matching

Education

- Patients are educated on their disease process and risk for disease recurrence
- Benefits of transplant versus dialysis
- Surgical risks, immunosuppression and side effects, possible rejection
- Benefits of living versus deceased donor transplants

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Evaluation Tests

- Physician History & Physical
- Psychosocial evaluation
- Dietary evaluation
- All female candidates will have a gynecological exam and PAP smear. Follow up GYN exams and pap smears will be done at intervals as clinically indicated, also as per recommendations by gynecologists and as per preventive care guidelines based on patients' age and risk factors
- All female candidates over age 40 must have a mammogram
- 12 lead EKG
- Echocardiogram
- Stress test
- Colonoscopy for patients > age 45 or with family history of colorectal cancer
- Obtain most recent lab values from the dialysis unit/Nephrologist office
- CBC
- Hepatitis B profile (HbsAB, HbsAG, HBCore Hbc AB total)) – If HBsAg is positive (+), then will require a liver biopsy.
- HIV antibody
- Drug Screening serum or urine
- Anti HCV
- Hepatitis C virus RNA quantitative. If result is positive (+), then test for hepatitis C genotype – will require liver biopsy and evaluation with Hepatologist
- Epstein Barr virus antibody
- CMV antibody
- RPR
- Varicella Antibody (IgG)
- PT, INR
- PTT
- TB testing (PPD)
- Chest X-ray
- All male candidates over age 40 must have a PSA
- C peptide
- Hgb A1C
- Histocompatibility testing

References

- Kidney transplantation in adults: Evaluation of the potential kidney transplant recipient - UpToDate

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Questions?

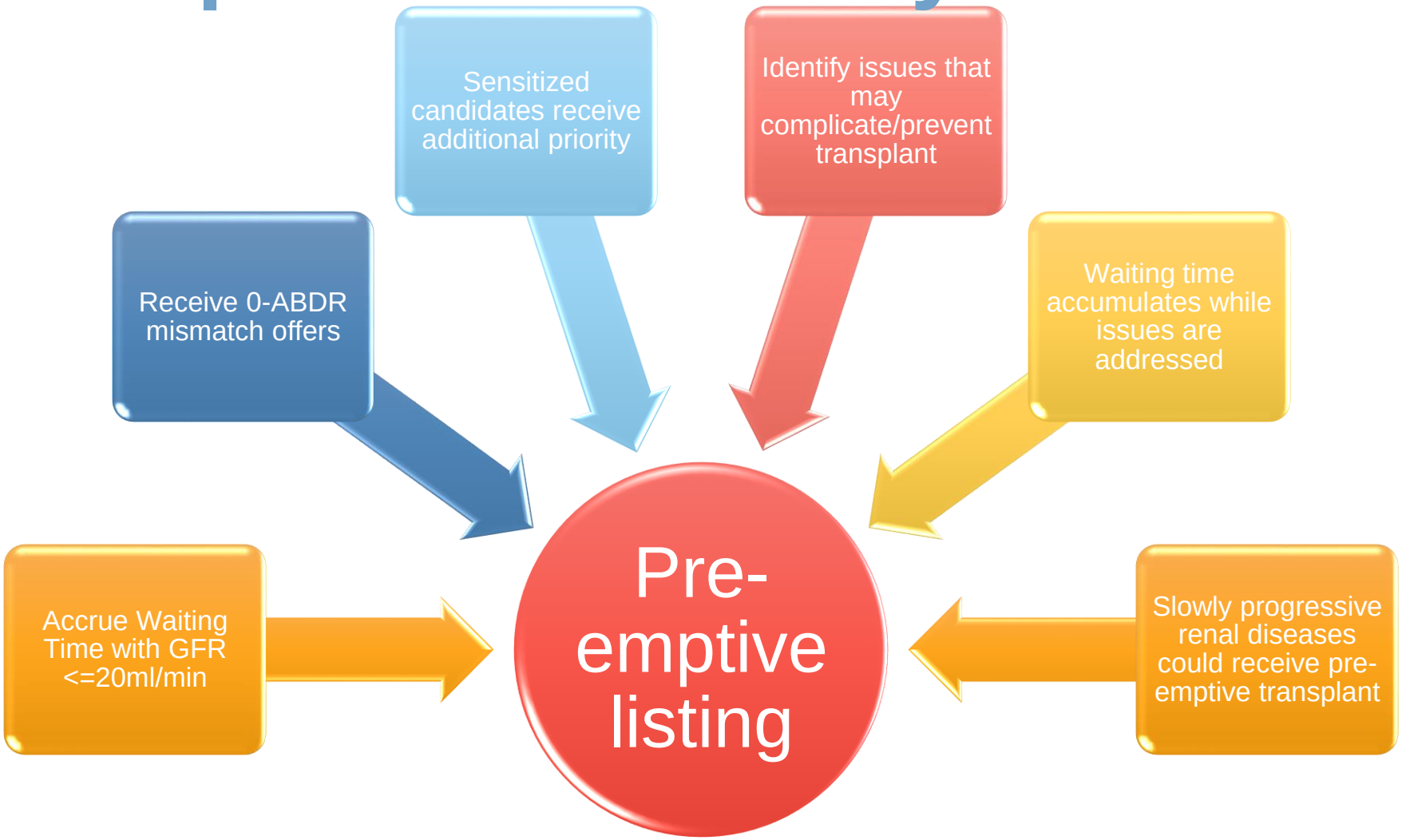
Evaluation for Transplant

Referral process, Evaluation Visit, and Waitlist Management

Allison Suboleski, BSN, RN
Jennifer Spencer, BSN, RN, CCTC

Disclosure

Importance of Early Referral



OPTN 2014

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Transplant Referral- Who

Who can refer a patient for transplant?

- Nephrologist
- Dialysis Staff Member
- Health Care Provider
- Self/patient

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Transplant Referral- When

- Patients initiated on maintenance dialysis should be referred for transplant within 28 days
- If patients are overwhelmed with recent diagnosis, follow-up and education should be ongoing
- After initial referral, should be reconsidered on an annual basis
- If prior non-candidacy was a result of psycho social or health issues that have been corrected or improved, re-consider
- Always consider patients who are new to your units
- Patients can be referred preemptively, with eGFR <30 (can be listed with eGFR , </=20)

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Transplant Referral- How

- Discuss transplant as a treatment option and provide education with your patients
- If a patient expresses interest, discuss local centers and the option of Multiple Listing. **Accessibility and convenience of the transplant center is important!**
- Once a patient's center(s) of choice is established, look at that center's criteria for evaluation and process of referral
- Encourage the patient to actively participate in the process
- If the patient does not meet the criteria of a particular center, assist with seeking additional centers as criteria can vary among Transplant Programs
- Document all interactions in the patient medical record

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How to Contact a Transplant Center

The process of referring patients varies at each transplant program

- Place a phone call
- Fax a referral
- Email a referral
- Submit an online referral

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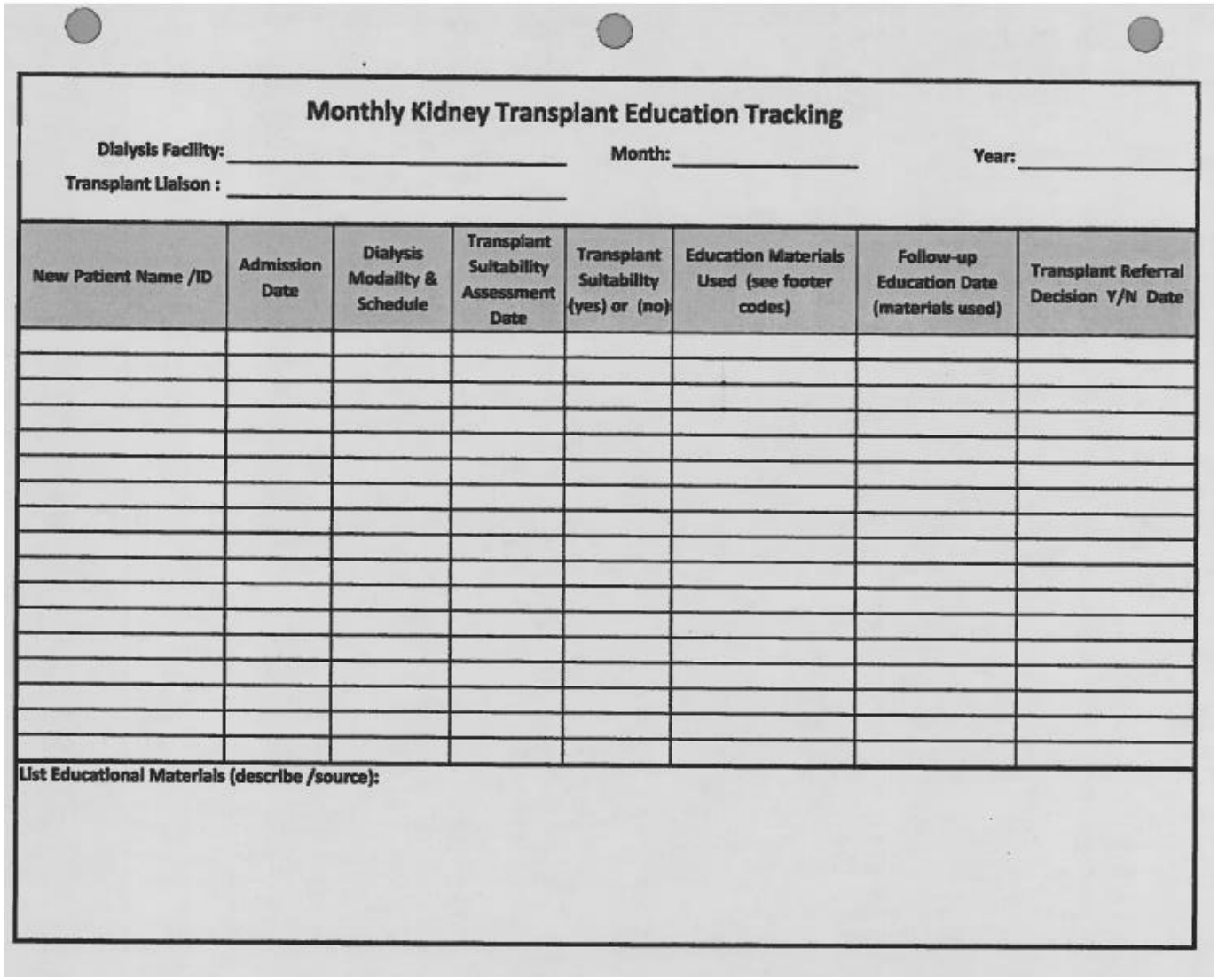
Documentation Tool



Monthly Kidney Transplant Education Tracking

Dialysis Facility: _____ Month: _____ Year: _____

Transplant Liaison : _____

New Patient Name /ID	Admission Date	Dialysis Modality & Schedule	Transplant Suitability Assessment Date	Transplant Suitability (yes) or (no)	Education Materials Used (see footer codes)	Follow-up Education Date (materials used)	Transplant Referral Decision Y/N Date

List Educational Materials (describe /source):

Key Points*** Transplant Referral

- Initiate a referral for transplant evaluation for all patients interested in a kidney or pancreas transplant
- Evaluate the patient's demographic area to choose the most convenient transplant program location for the patient
- Each transplant center has different selection criteria for accepting patients
- If a patient is ineligible at one transplant center they may be eligible at another one
- Physicians, nurses, social workers and even the patient may initiate referral to a transplant program for evaluation

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Patient Status

Referral- Contact made with center, no appointment completed

Evaluation- Patient has had a pre-transplant evaluation appointment completed and has not been placed on waiting list

Candidate ***Both Status 1 and 7, they continue to accrue waiting time daily

- Active- Status 1
- Inactive- Status 7

Non-Candidate

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Patient Education Re: Evaluation

Meeting with team

- Nurse Coordinator, Social Worker, Dietitian, Physician, Financial Coordinator

Duration

- Initial visit generally 3-4 hours

Education provided- Pre-Transplant, Operative and Post-Transplant follow-up

Planned Evaluation Testing

Communication with Team Members

Importance of Early Education

- Ensures that patients have an understanding of the treatment plan
- Allows patients and their support system to make informed decisions regarding transplant as a treatment option
- Informs patients of what is required of them throughout the process
- Introduces the topic of living kidney donation, allowing for early identification of potential living donors

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Patients are Educated on SRTR Data

- Public reports by the US Scientific Registry of Transplant Recipients(SRTR) are used by regulatory agencies, private insurance providers, transplant centers and patients
- These reports are published every six months showing the latest data
- Data can be retrieved at www.srtr.org

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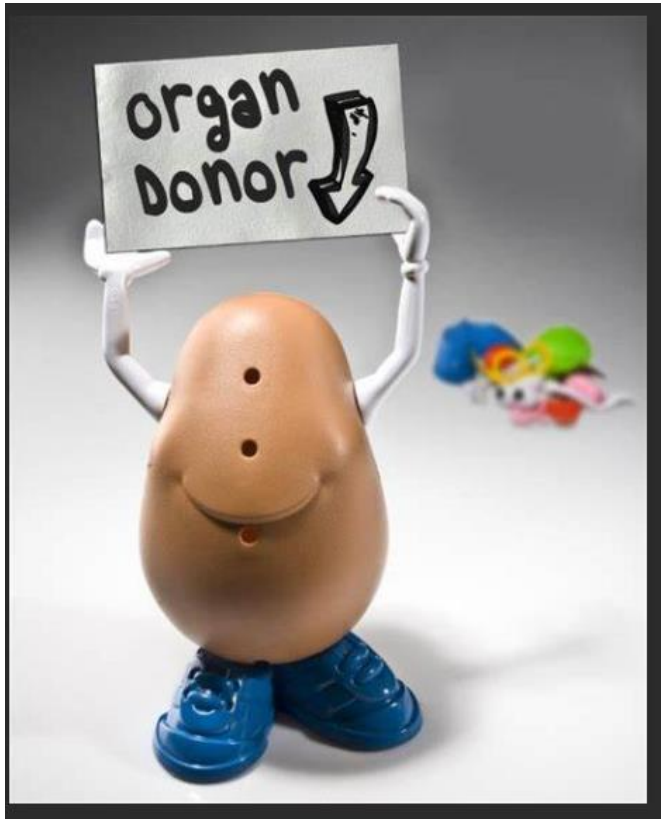
Various Donor Types



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Types of Kidney Transplant Donors

- **Deceased Donor Transplant**
  - **KDPI ≤ 85**
    - *Kidney with a low donor risk*
  - **KDPI 85 or greater**
    - *Kidney with an increased donor risk*
  - **Donation after Cardiac Death (DCD)**
    - *Non-heart beating donor, meeting death criteria with the cessation of circulation*
- **Living Donor Transplant**

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2020 PHS Identified Risk Organ Donors for the Transmission of Acute HIV, HBV, and/or HCV Infection

- Risk criteria (during the 30 days before organ procurement):
- 1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection
- 2. Man who has had sex with another man
- 3. Sex in exchange for money or drugs
- 4. Sex with a person who had sex in exchange for money or drugs
- 5. Drug injection for nonmedical reasons
- 6. Sex with a person who injected drugs for nonmedical reasons
- 7. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours
- 8. Child breastfed by a mother with HIV infection 9. Child born to a mother with HIV, HBV, or HCV infection 10. Unknown medical or social history

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A2/A2B Donor Consent/ABO Incompatible Transplant

- Blood Group A can be further subtyped as “A1” or “A2”
- For the A2/A2B donor, often the general population has a low level of antibodies against the A2/A2B donor. These antibodies are tested as “anti-A1 or non-A1 titers”
- With low level of recipient titers, the A2/A2B donor can be recognized almost an “O” donor and are allocated to certain blood group B recipients due to the challenges with blood group B matching
- Having acceptable titers is determined pre-transplant at the time of crossmatch
- In addition to ABO verification process, ABO subtype verification must also be done
- Patients are educated regarding any future blood product transfusions and provided with an identification/safety information card post-op

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Donor with a Positive Core Antibody for Hepatitis B

- Donor has had Hepatitis B in the past. Transplanting an organ from this type of donor has a low chance of giving Hep B infection to the recipient, especially if the recipient has received the Hep B vaccine

- Rate of transmission ranges from less than 1% to 20%

- If recipient does not have Hep B antibodies, they can still be offered this type. Post-transplant, vaccination can be administered, or medication can be given that may prevent recipient from being infected with Hep B

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Hepatitis C Donors

- Hepatitis C infected donor (NAT positive) for a Hepatitis C infected Recipient (NAT positive)
- Hepatitis C Antibody Positive Donor (non-viremic) for a NAT negative donor
- Hepatitis C infected donor (NAT positive) for a NAT negative donor
- These donors may or may not also be considered PHS increased risk

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Candidacy

Candidacy is a process determined by a Multidisciplinary Team, and not one person

- Social Workers
- Surgeons
- Transplant Nephrologists
- Pharmacists
- Nurse Coordinators
- Dietitian
- Financial Coordinator

Key Points Evaluation Status

- Patient is placed in evaluation status from time of visit until they are placed on waitlist or deemed not suitable to be a candid
- Goal of evaluation period is 90 days, may vary between
- Transplant center facilitates testing with the exception o mammograms, PAP smears, and colonoscopies which should be arranged through the patients PCP
- Often these test can cause delays in being listed so please encourage all of your patients to complete
- Dental issues and smoking cessation can further delay listing
- When placed on the list, the listing letter will be sent to the dialysis unit

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Wait List Status: Active vs. Inactive

Active status (status 1)

- Patient accrues time on wait list
- Can receive organ offer notifications at any time

Inactive (status 7)

- Patient accrues time on wait list
- Unable to receive organ offer notifications

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Reasons Patients Experience Status Changes
Status 1/7

- Medical suitability (hospitalizations, infection, abnormal testing
- Incomplete testing
- Malignancy
- Compliance Issues
- Travel
- Insurance Changes
- Medications

***Inactive status (status 7) continues to accrue waiting time

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Key Points Communication

- Please Communicate with Transplant Center:
  - Issues with compliance
  - Changes in insurance
  - Patient changes units
  - Hospitalizations
  - Blood Transfusions
  - Changes in medications such as blood thinners, midodrine therapy
  - Significant changes in BMI

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Communication

- Please notify the transplant center if any patient listed for transplant has experienced any change in health, insurance, or contact information
- Patients and hospitals do not notify the transplant center
- If patient has expired, please notify transplant center

Resources:

Jones JM, Kracalik I, Levi ME, et al. Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep 2020;69(No. RR-4):1–16.

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Questions?

Pre-Transplant Pharmacologic Risk Assessment

Della Xu, PharmD

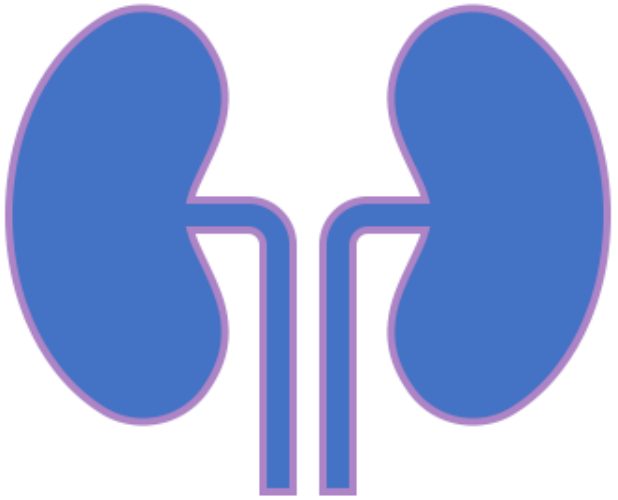
Solid Organ Transplant Pharmacist

Disclosure

Evaluation of Transplant Candidate

- Evaluations from many disciplines to determine if the patient has the mental, social, physical, financial, and medical readiness to have a successful post-transplantation outcome

- **Critically assess the presence of pharmacotherapy issues**



Maldonado AQ et al. Am J Health Syst Pharm. 2015 May 15;72(10):781-93

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Assessment of Pharmacologic Risk

- Medication allergies
- Medications related to mental health
- Anticoagulation
- Medications for chronic pain
- Hormonal contraception and replacement therapy

Maldonado AQ et al. Am J Health Syst Pharm. 2015 May 15;72(10):781-93

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Assessment of Pharmacologic Risk

Current use of immunosuppressants

- Corticosteroids
  - Prednisone
  - Methylprednisolone
- Anti-tumor necrosis factor (a-TNF)
  - Etanercept (Enbrel®)
- Monoclonal antibodies
  - Adalimumab (Humira®)
  - Infliximab (Remicade®)

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Assessment of Pharmacologic Risk

Identify potential drug-drug interactions with immunosuppressant medications

- Azole antifungals (itraconazole, voriconazole)
- Non-dihydropyridine calcium channel blockers (verapamil, diltiazem)
- Macrolide antibiotics (erythromycin, clarithromycin)
- Anti-epileptics (carbamazepine, phenytoin)

Zhou SF et al. Ther Drug Monit. 2007 Dec;29(6):687-710

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Assessment of Pharmacologic Risk

Identify potential pharmacodynamic interactions

- Enhanced nephrotoxicity
  - NSAIDs

- Enhancing the immune system
  - Herbal products including ginseng, Echinacea, high dose vitamin E
  - Just say NO to herbals

Carrillo-Vico A et al. Buffering the Immune System. International Journal of Molecular Sciences. 2013 04/07;14(4):8638-83
Maldonado AQ et al. Am J Health Syst Pharm. 2015 May 15;72(10):781-93
Kang S et al. J Ginseng Res. 2012 Oct;36(4): 354-368

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Common Post-Transplant Immunosuppression

Induction Therapy

- Initiated intraoperatively or immediately postoperatively and is concluded within the first week or two after transplantation
- More commonly refers to administration of antibodies against specific or multiple antigenic targets of immune cells in the immediate perioperative period
- Commonly used induction agents:
  - Thymoglobulin® (rabbit anti-thymocyte globulin (rATG)
  - Simulect ® (basiliximab)
  - Campath ® (alemtuzumab)

Halloran PF et al. N Engl J Med. 2004 Dec 23;351(26):2715-29

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Maintenance Immunosuppression

- Less potent prophylactic therapy used throughout the life of the transplanted organ to prevent late acute rejection and improve graft survival
- Agents
  - Calcineurin Inhibitors
    - Tacrolimus, Cyclosporine
  - Antimetabolites
    - Azathioprine, Mycophenolate mofetil/sodium
  - mTOR Inhibitors
    - Sirolimus, Everolimus
  - Corticosteroids
  - Co-stimulatory Inhibitor
    - Belatacept

Halloran PF et al. N Engl J Med. 2004 Dec 23;351(26):2715-29

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Balancing Act

- Rejection
- Graft loss

- Infection
- Malignancy
- Side effects

Halloran PF et al. N Engl J Med. 2004 Dec 23;351(26):2715-29

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Conclusion

- Identify possible drug-drug interactions prior to transplant

- Consensus opinions of practitioners in transplantation pharmacy regarding the pharmacologic and non-pharmacologic factors that should be considered in assessing candidates for transplantation

Maldonado AQ et al. Am J Health Syst Pharm. 2015 May 15;72(10):781-93

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Questions?

Obesity
And
Kidney Transplantation

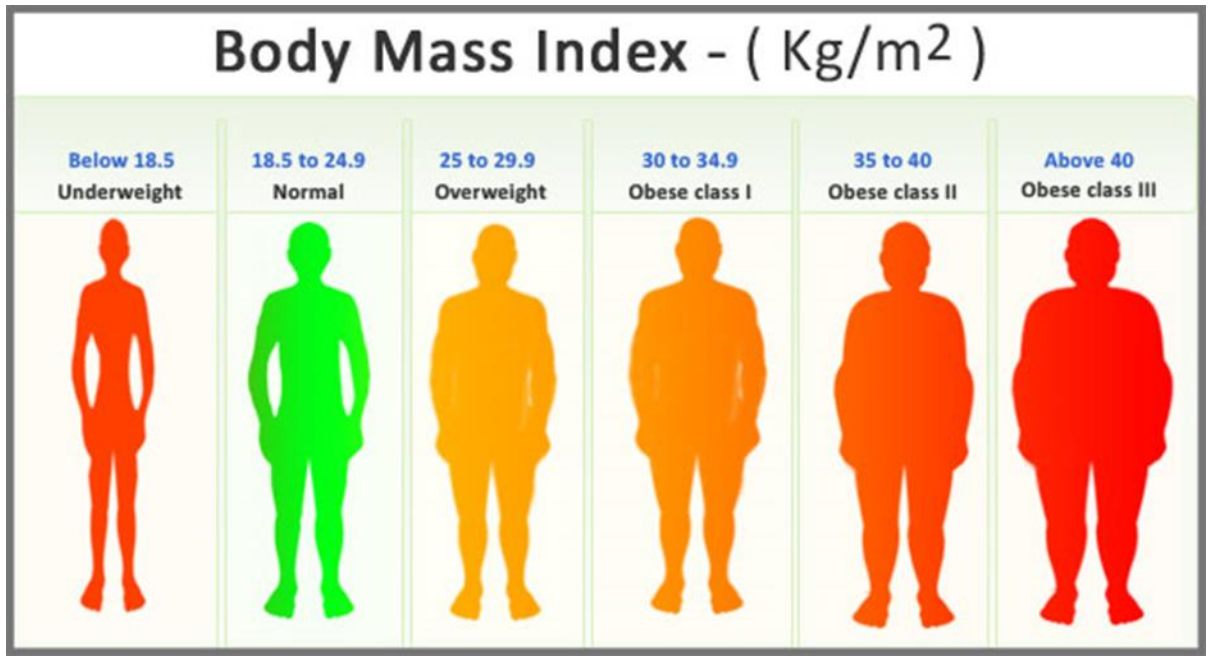
Mary Nell Tabayoyong MS, RD
Transplant Dietitian
Virtua Our Lady of Lourdes

Virtua Health

Disclosure

Defining Obesity with Body Mass Index

$$BMI = \frac{\text{weight (kilograms)}}{\text{height}^2 \text{ (meters)}}$$



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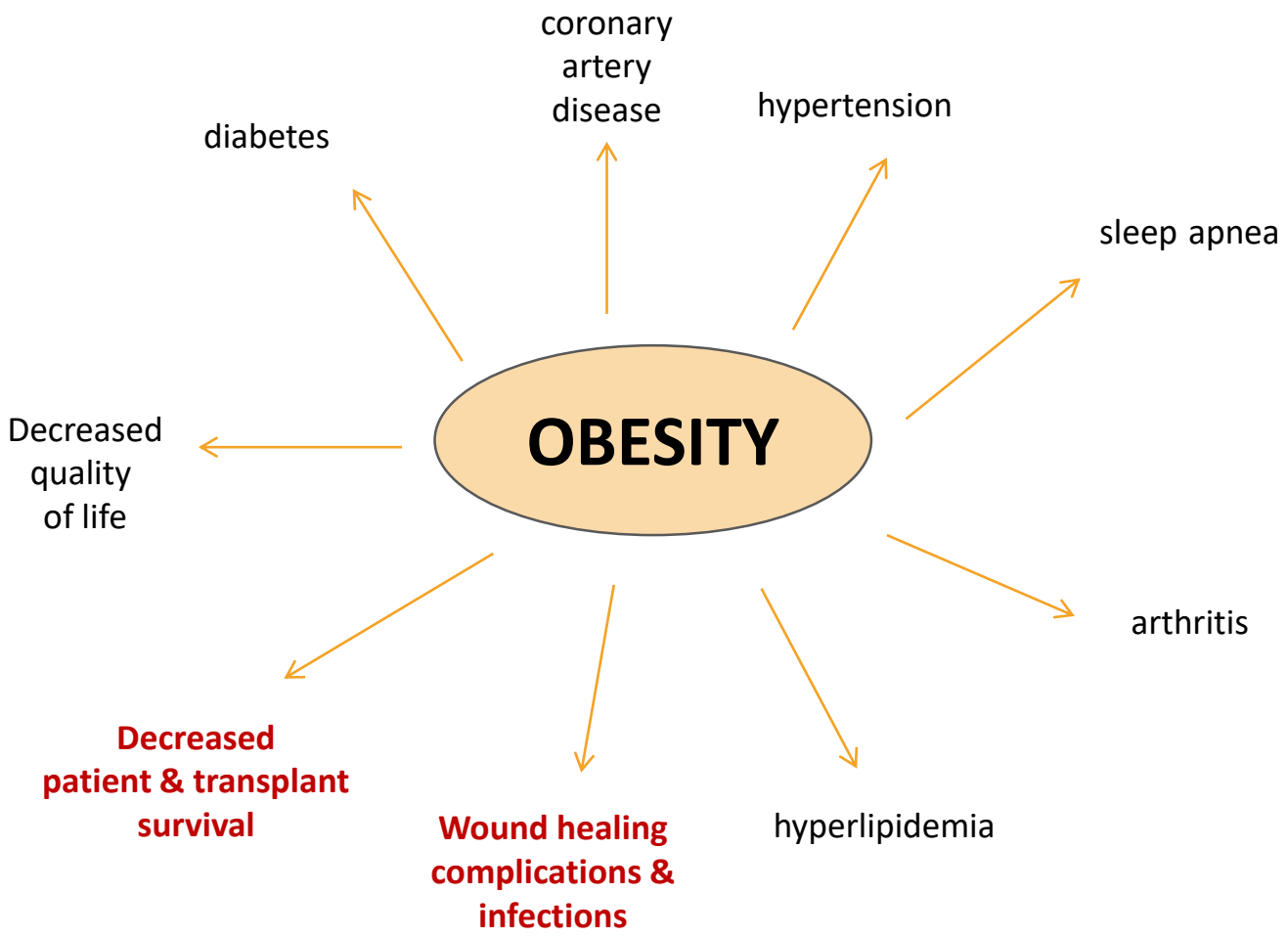
Consequences of Obesity



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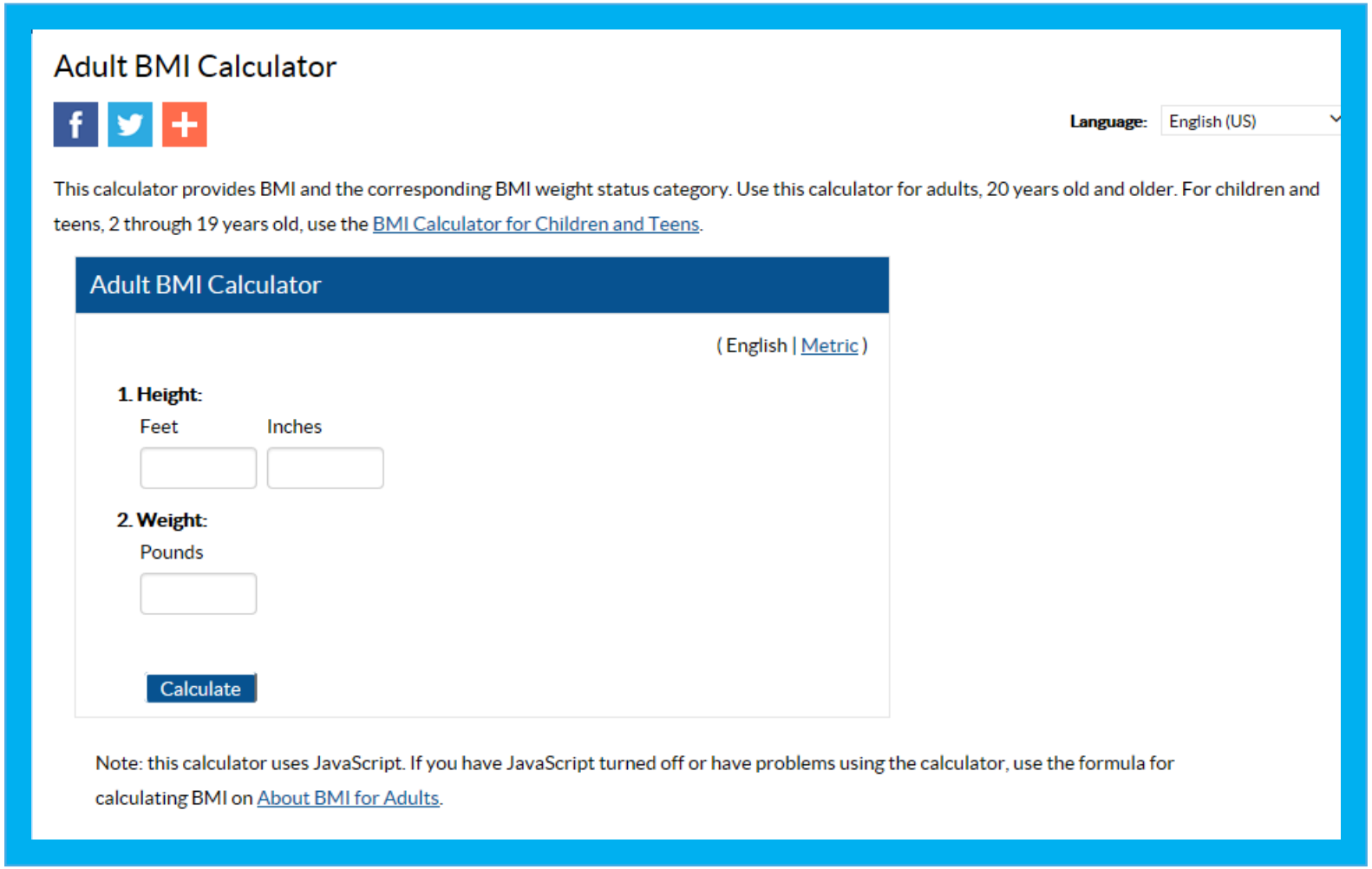
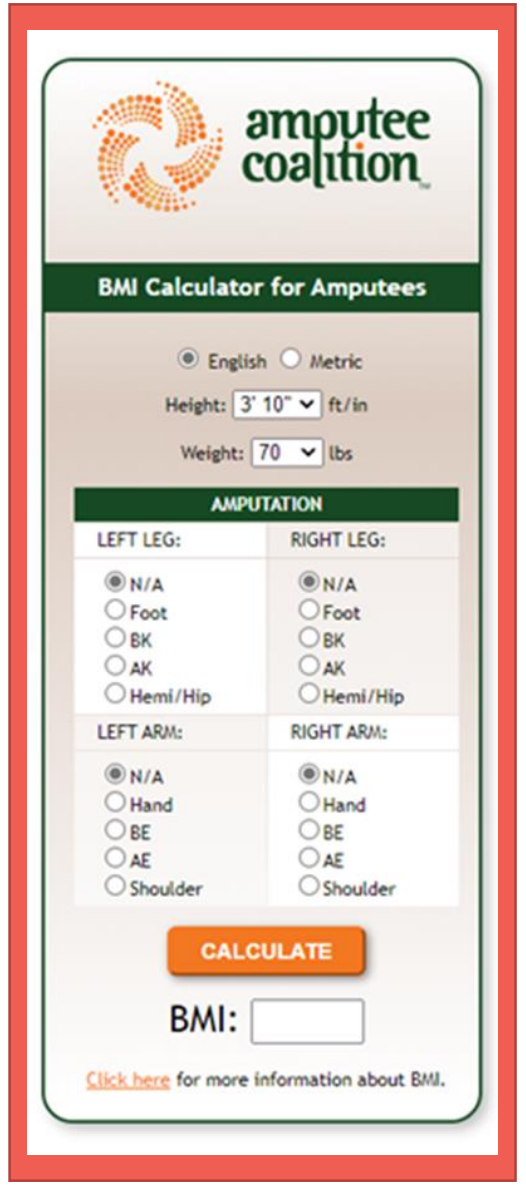
Adult BMI Calculators



https://www.cdc.gov/



https://www.amputee-coalition.org

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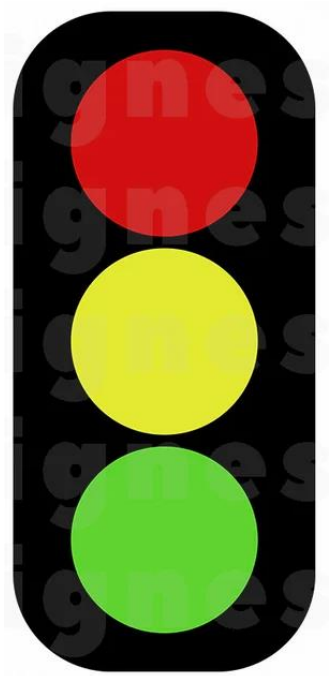
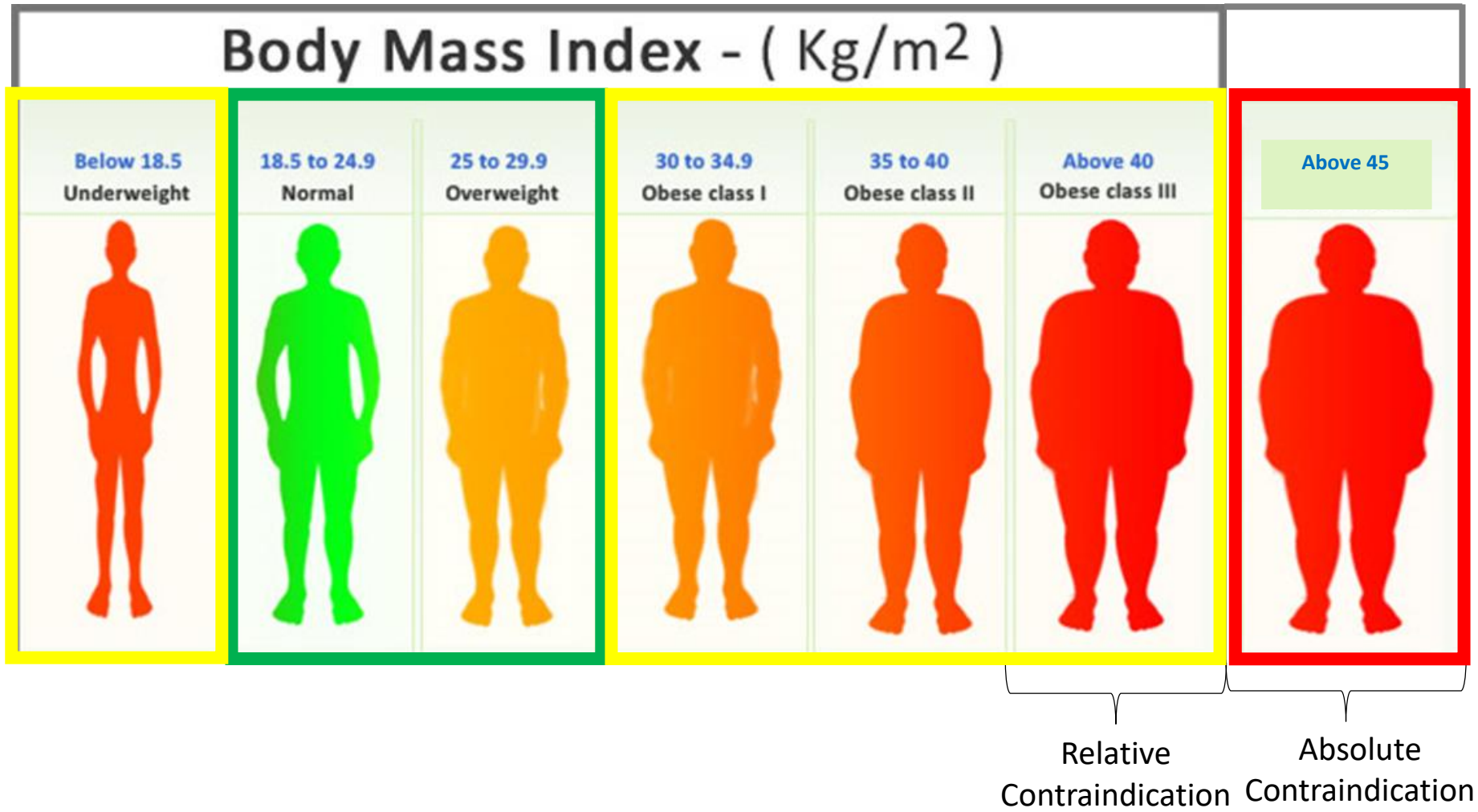
BMI as a Screening Tool





Goals & Nutritional Considerations After a Kidney Transplant

GOAL #1 Maintain a Healthy Weight

GOAL #2 Control Blood Sugar Levels

GOAL #3 Healthy Blood Lipid Levels

GOAL #4 Control Blood Pressure

GOAL #5 Bone Health

Other Considerations

- Avoid herbal supplements due to the risk of affecting your transplant medicines.
- Avoid grapefruit and grapefruit juice since these affect many transplant medicines.
- Follow food safety guidelines such as avoiding undercooked meats, poultry, eggs, raw fish such as sushi or sashimi, and raw milk and unpasteurized dairy products.
- Choose healthy, fresh foods when possible.
- Do regular physical activity.

Academy of Nutrition and Dietetics (RPG) Renal Dietitians 2015

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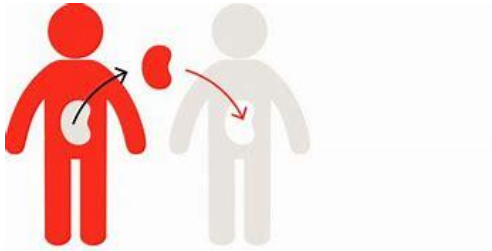
Questions?



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Social Considerations & Kidney Transplantation

Jamie Hoyle, LSW

Transplant Social Worker

Disclosure

Transplant Social Work Role

Conduct psychosocial assessments on patient's to assess needs and potential psychosocial barriers to transplant

Collaborate with dialysis clinics regarding compliance and treatment

Give resources and make referrals to assist patient's in having the support they need

Provide education and support regarding transplant process

Collaborate with providers and multidisciplinary transplant team

Potential Psychosocial Barriers

Physical concerns

- Medical diagnosis
- Physical functioning/activities of daily living

Housing

- Stability & location

Support System

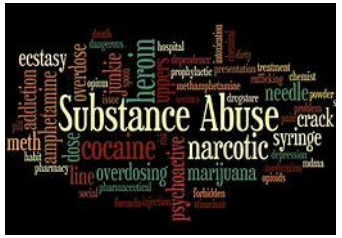
- Family history
- Relationships with family members or friends
- Marital status/children

Mental health

- Mental health diagnosis/treatment

Substance Use/Abuse

- Past or present alcohol use
  tobacco use, and
  other substances



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Employment, Finances, & Insurance

Work History

Will need 6-8 weeks off work after surgery

Eligibility FMLA/STDI

Has patient looked into this or spoken to job?

Income/month

Is patient making an income?

Insurance Coverage

Premium/copays

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Post Transplant

Hospitalization

First 1-2 days ICU

4-7 days @ hospital

Transportation/access to care

What is patient's plan for getting to hospital & post appointments

Eligibility for medical transport

No driving 4-6 weeks

Follow up Appointments

month 1- 2x a week

month 2- 1x a week

month 3- 1x every other week

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Questions?

Medical Insurance and Financial Considerations in Kidney Transplant

LaWan Johnson – Transplant Financial Assistant

Disclosure

“Because donated organs are a severely limited resource, the best potential recipients should be identified. The probability of a good outcome must be highly emphasized to achieve the maximum benefit for all transplants”

UNOS Ethics Committee

Background

- 106,670 patients are waiting for transplantation (Oct, 2021)
- 17 people die each day waiting for an organ transplant
- Due to the limited organs available for transplantation, a thorough evaluation of transplant candidates is required to ensure each organ recipient will care for the organ and have the best possible post-transplant outcome.
- In addition, there are significant financial and time resources involved in organ transplantation and subsequent care which highlight the importance of identifying appropriate candidates for transplant and ensuring before surgery that such resources are available to patients.

Review of the Literature

- Shows there are several psychosocial factors known to contribute to poor patient and graft outcomes. They include:
  - Poor social support/absence of family caregiver
  - Mental/psychiatric disorders likely to negatively affect post transplant adherence
  - Self-destructive behavior such as alcohol or substance abuse
  - A history of poor adherence with medical and mental health treatment
  - The patient's inability or unwillingness to comprehend the need for improved adherence
  - Dysfunctional personality traits and disorders, and
  - Financial issues which could interfere with post-transplant medication adherence

Policy

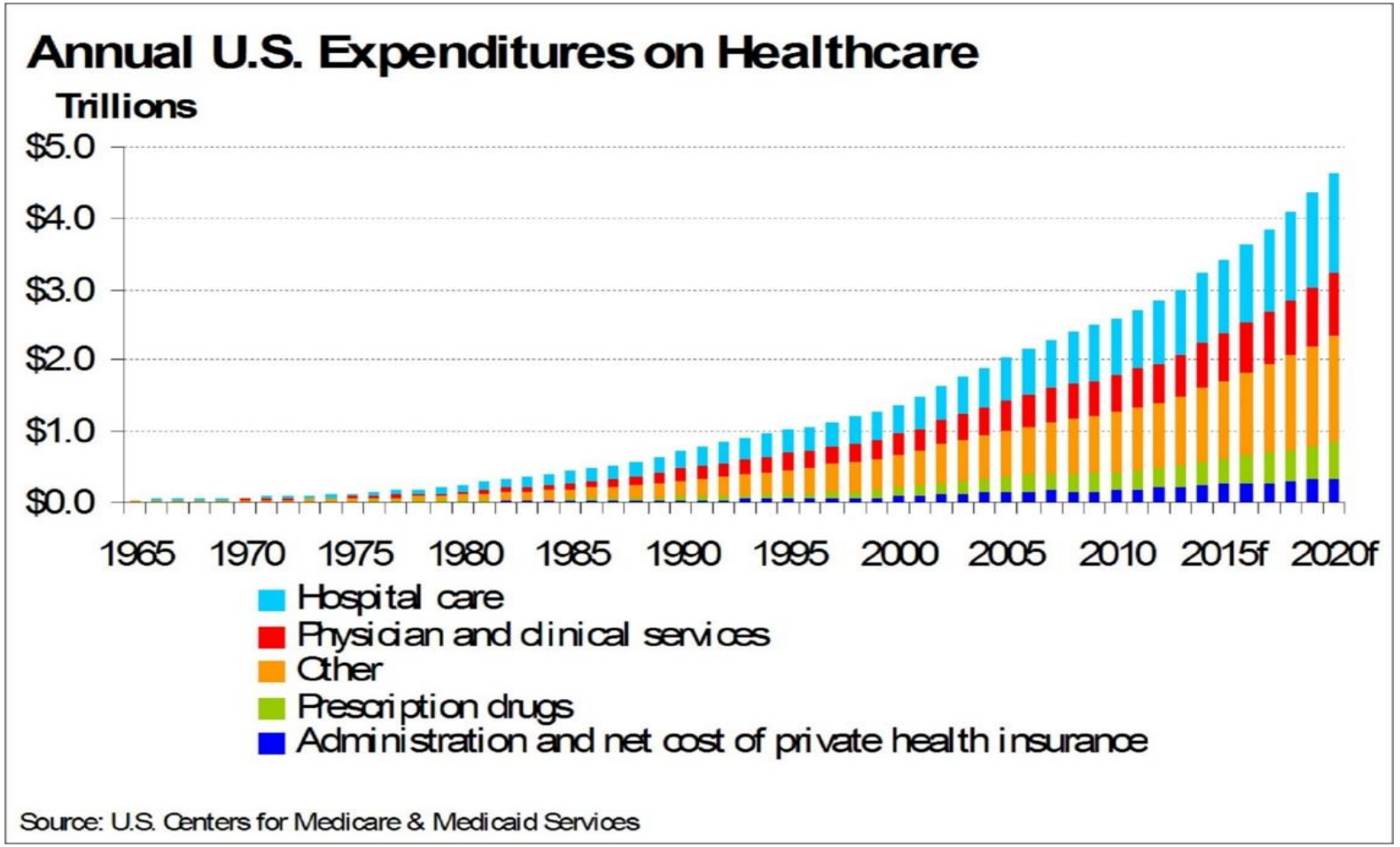
U.S. Department of Health and Human Services (DHHS) Transplant Center Process Requirements

"Prior to placement on the center's waitlist, a prospective transplant candidate must receive a psychosocial evaluation".

Centers for Medicare and Medicaid Services (CMS)

- *Transplant team: The transplant center must identify a multidisciplinary transplant team and describe the responsibilities of each member of the team*
- *The transplant center must make available social services, furnished by **qualified social workers**, to transplant patients, living donors, and their families. Definitions for a qualified social worker included:*
  - *A qualified social worker is an individual who meets licensing requirements in the state in which he or she practices and*
  - *(1) has completed a course of study with specialization in clinical practice and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education, or,*
  - *(2) is working as a social worker in a transplant center as of the effective date of this final rule and has served for at least 2 years as a social worker, 1 year of which was in a transplantation program, and has established a consultative relationship with a social worker who is qualified under § 482.94(d)(1).*

Rise in HealthCare Cost



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Role of the Transplant Financial Assistant

- Work with the Medical Team to obtain demographics
- Verify benefits; review the available benefits
- Is patient eligible for Transplant
- Do they meet criteria for Medical Team/Insurance
- Is there a concern for Social Work or TFC, how can we partner together to get pt. transplanted?
- Does the pt. require assistance? Additional coverage, exception to policy, etc.

UNOS Says

- Social workers and financial coordinators collaborate to determine how our patients can best afford the costs of transplantation.

  - SW have some knowledge about insurance policies and funding but the financial coordinator has detailed knowledge of financial matters and hospital billing methods.

What are the Most Common Financial Barriers to Transplant?

- *No hope of coverage*
- Poor coverage
- Inability to afford Out of Pocket
- Travel and lodging
- Reduced or lost income
- Uncovered expenses

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Who Pays for Kidney Transplants?

- Medicare – Federal Funded
- Employer Sponsored or Commercial Insurance Plans
- Medicaid – State Funded
- Medicare Supplemental or Retirement Plans

Pre-Transplant Evaluation

- Medical and prescription benefits are verified before evaluation
- Transplant insurance benefits are reviewed and recommendations are made for additional services if needed
- For patients with Medicare/Medicare Advantage plans the evaluation/testing cost are billed to the organ acquisition account and not billed to the patients insurance
- For patients with commercial/Medicaid plans the evaluation/testing costs are billed to the recipients insurance

Living Donation: Pre Evaluation

What to expect during pre evaluation

- Discuss with donor how transplant billing is done related to the donor
- Services related to the evaluation are billed to the kidney acquisition account
- Other health issues the donor may have will be billed to their insurance

Living Donation: Surgery and Post Transplant

Will the donors incur any cost?

- The living donation surgery, called a nephrectomy, is billed to the recipients insurance company
- Follow up for the nephrectomy will not be billed to the donor's insurance company
- Office visited and any other charges related to the donation are billed to the recipients insurance

Transplant Operation

- The charge for the inpatient admission for transplant is sent to the insurance company
- The transplant is paid according to the patients specific transplant benefit of the health plan

Medicare Coordination of Benefits

1. Working Aged (Medicare beneficiaries age 65 or older) and Employer Group Health Plan (GHP):
    - Individual is age 65 or older, is covered by a GHP through current employment or spouse's current employement AND the employer has less than 20 employees:

    Medicare pays Primary, GHP pays secondary

- *Individual is age 65 or older*, is covered by a GHP through current employment or spouse's current employment AND *the employer has 20 or more employees (or at least one employer is a multi-employer group that employs 20 or more individuals):*
  GHP pays Primary, Medicare pays secondary
- *Individual is age 65 or older*, is *self-employed* and covered by a GHP through current employment or spouse's current employment AND *the employer has 20 or more employees (or at least one employer is a multi-employer group that employs 20 or more individuals):*
  GHP pays Primary, Medicare pays secondary

2. Disability and Employer GHP:

- *Individual is disabled*, is covered by a GHP through his or her own current employment (or through a family member's current employment) AND the employer has 100 or more employees (or at least one employer is a multi-employer group that employs 100 or more individuals)
  GHP pays Primary, Medicare pays secondary

3. End-Stage Renal Disease (ESRD):

- Individual has ESRD, is covered by a GHP and is in the first 30 months of eligibility or entitlement to Medicare
  GHP pays Primary, Medicare pays secondary during 30-month coordination period for ESRD
- Individual has ESRD, is covered by a Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA plan) and is in the first 30 months of eligibility or entitlement to Medicare
  COBRA pays Primary, Medicare pays secondary during 30-month coordination period for ESRD

Reasons you Can Qualify for Medicare

- Age 65
- ESRD
- Social Security Disability collection for at least 2 years
- Medicare entitlement is not limited by other insurance enrollment

Difference Between SSI and SSDI

SSI

- SSI you must be disabled, but do not have to meet the work history criteria.
- Smaller amount approved 750.00 a month for individuals and 1125.00 for couples. Children that are dependents receive 376.00 for each child.
- SSI comes with Medicaid eligibility
- No waiting period once medically eligible
- Must have resources less than 2,000.00 for an individual or 3,000.00 for a couple
- https://www.ssa.gov/ssi/text-resources-ussi.htm

SSDI

- 6 Month wait period
- After 24 months eligible for Medicare
- Based on work history and credits on how much $$ received
- No resource limit and if married spouse can still work no income limit for other household dependents.

Things to Know About Medicare

- You must have sufficient work history AND a legal resident of the U.S. for at least five years

Work credits needed for disability benefits

Social Security
The Official Website of the U.S. Social Security Administration

The rules are as follows:

- **Before age 24**--You may qualify if you have 6 credits earned in the 3-year period ending when your disability starts.
- **Age 24 to 31**--You may qualify if you have credit for working half the time between age 21 and the time you become disabled. For example, if you become disabled at age 27, you would need credit for 3 years of work (12 credits) out of the past 6 years (between ages 21 and 27).
- **Age 31 or older**--In general, you need to have the number of work credits shown in the chart below. Unless you are blind, you must have earned at least 20 of the credits in the 10 years immediately before you became disabled.

Born after 1929, Became Disabled At Age:	Number of Credits You Need:
31 through 42	20
44	22
46	24
48	26
50	28
52	30
54	32
56	34
58	36
60	38
62 or older	40

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What is ESRD Medicare?

- Medicare has specific guidelines for people who have End Stage Renal Disease
- Patients can qualify after starting dialysis or receiving a kidney transplant

When Does it Start?

- The month peritoneal dialysis training is received
- 3 months after starting hemodialysis
- The first day of the month a kidney transplant was performed

Medicare: 2 Parts for Medical Coverage

Medicare Part A

- Pays for inpatient hospital stays
- Patient is responsible for 1,484.00 deductible per year
- There is no premium for Part A

Medicare Part B

- Pays for physician outpatient and dialysis services
- 203.00 annual deductible
- In 2021 the monthly premium is 148.50 (or higher depending on your income)

Medicare Part D - Prescriptions

- Medicare Part D is the prescription plan that is offered to all Medicare enrolled patients
- The plans are administered by various commercial payers
- There are monthly premiums for coverage
- The plans also have a coverage gap where you will pay a higher portion of assigned charges
- You do not have to enroll in Part D if you have prescription coverage from your employer or your spouse

What is a Donut Hole?

NO, IT IS NOT THE CENTER OF A DONUT THAT YOU EAT!

•For 2021 Medicare Part D they have initial coverage, donut hole, and catastrophic.

•During the initial coverage they pay 25% by the beneficiary and 75% of the cost of generic.

•Once the patient reaches 4130.00 this is considered the donut hole. The patient pays 30% brand name. Once the patient reaches 6550.00 out of pocket the patient is considered catastrophic and the patient pays 5% or 3.70 for generic and 5% or 9.20 for brand whichever is greater.

•This starts over every Jan 1st.

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Medicare Part B vs D Medications

Immunosuppressive Drugs for transplant patients

- Medicare Part B covers immunosuppressive drugs if you had a transplant in a Medicare-certified facility and you were enrolled in Medicare Part A at the time you got the transplant.

- Medicare part D covers immunosuppressive drugs if you were not enrolled in Medicare Part A at the time you had a transplant or you had a transplant at a non-Medicare- certified facility

Medicaid – State Funded

- Each state maintains their own Medicaid program
- The State offers different programs for various needs
- NJ PAAD and Senior Gold – can assist patients with prescription drug costs
- Qualified Medicare Beneficiary – Assists with Medicare premiums, deductibles, and co-insurance
- Special Low Income Medicare Beneficiary & Qualified Individual – assists with Medicare B premium only.
- There are specific income guidelines to qualify

Additional Resources

- Social Security Extra Help – will assist with the Medicare D coverage gap and premium costs

- Pharmaceutical Companies – offer assistance for the cost of immunosuppressive medications

Post Transplant Services

- If you have an AKF funded plan the AKF plan will not continue to pay for premium after transplant
- Transplant office visits will be billed to your insurance company and you will be responsible for any copays and/or co-insurance
- Immunosuppressive medications are medically necessary and depending on insurance coverage, may carry significant costs
- Adequate and continued insurance coverage is essential to a successful transplant

Resources

- Medicare Eligibility due to ESRD and or Disability
- https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/End-Stage-Renal-Disease-ESRD/ESRD.html
- Medicare in Living Donor
- NJ PAAD & NJ Senior Gold
- http://www.state.nj.us/humanservices/doas/services/paad/
- http://www.state.nj.us/humanservices/doas/services/seniorgold/
- NJ Workability program
- http://www.state.nj.us/humanservices/dds/projects/discoverability/
- Medicare Extra Help
- https://www.ssa.gov/pubs/EN-05-10525.pdf
- Fundraising
- https://helphopelive.org/
- http://www.transplants.org/patient-fundraising

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Important Dates to Remember

- ACA Open Enrollment – November 1st-December 15th
- Medicare Part D Open Enrollment – October 15th-December 7th to be effective Jan 1st
- Medicare Part B Open Enrollment – Jan 1st- March 31st to be effective July 1st
- Special enrollment – can be anytime that patients lost comprehensive coverage they are eligible to enroll within the last 63 days
- Patients have 6 months to enroll in a Medigap plan if life changing events or becoming eligible. They can enroll after that, but maybe subject to medical underwriting and companies can deny coverage.
- If patients do not enroll in Medicare and do not have comprehensive coverage they will be penalized 10% for each year not enrolled for Part B premium and Part D premium.

- If patient has deferred Medicare due to ESRD they may enroll at any time without penalty. If they enroll in Part A only they must wait for open enrollment for Part B.

    - Of note – they may go back 12 months eligibility; therefore, they can retract Medicare Part A and enroll in Medicare part A/B up to 12 months retro. They must pay the Part B premium for all of those previous months.

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Questions?

Short and Long Term Complications of Transplant

Nasser Youssef, MD

Disclosure

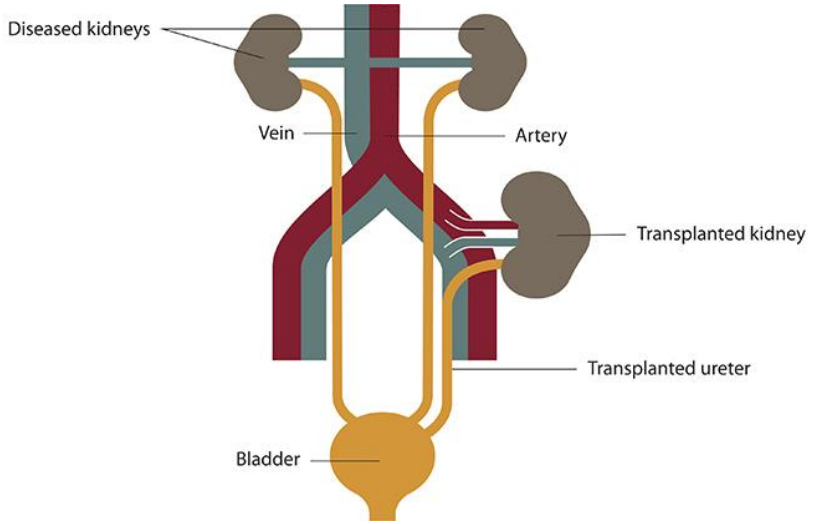
History of Kidney Transplantation

1902 - First kidney transplantation successfully performed in a dog in a Medical School in Vienna Austria (2).

1945 - First temporary kidney transplant is performed at Peter Bent Brigham Hospital (now Brigham & Women's Hospital in Boston (2).

1952 - The first successful kidney transplant surgery performed from a mother fatally injured in a traffic accident. Her kidney was transplanted into her son. The kidney functioned well for 22 days (2).

1954 - First live donor human kidney transplant. identical twin brothers, performed in Boston, MA. The transplanted kidney functioned for 8 years (2).



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Operative Technique

All kidney transplant patients are treated with immunosuppressive therapy prior to surgery. Many patients may be anemic and malnourished. Due to this, wound healing is potentially compromised. Therefore, the following are essential:

- Meticulous surgical technique
- Attention to detail
- Strict aseptic technique
- Perfect hemostasis

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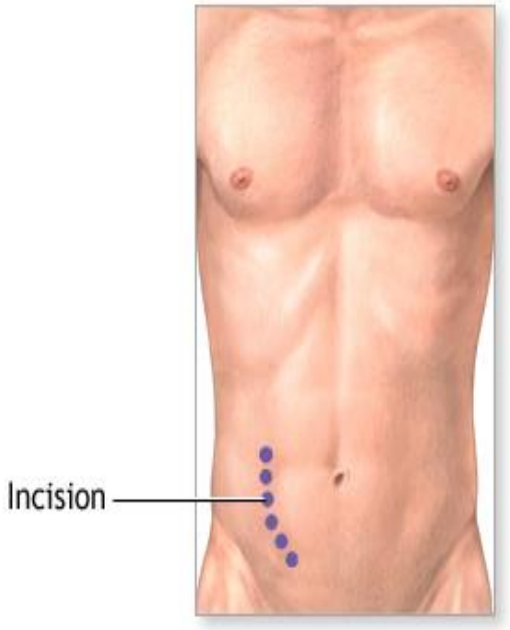
Operative Technique, *Incision*

- An oblique incision is made from the symphysis in the midline curving in a lateral superior direction to the iliac crest.

- The retroperitoneal space is entered and a pocket is made for the kidney.

- In patients with type 1 diabetes, who may be eventually candidates for pancreas transplant, the **kidney** is preferentially placed in the **left iliac fossa** to facilitate a possible pancreas transplant on the right. 1



ADAM.

Operative Technique, *Vascular Connections in a Living Donor*

Renal Vein

- Sewn to the **external iliac vein**.
- If there are multiple renal veins, the largest may be used

Renal Artery

- Sewn to the **external iliac artery** in an end to side fashion
- May also be sewn to the **hypogastric artery** in an end to end fashion

Ureter

- Anastomosed to the recipient **bladder**
- Or ipsilateral native ureter as ureterostomy
- Leadbetter-Politano technique, Lich-Gregoir technique, Shanfield technique (1).

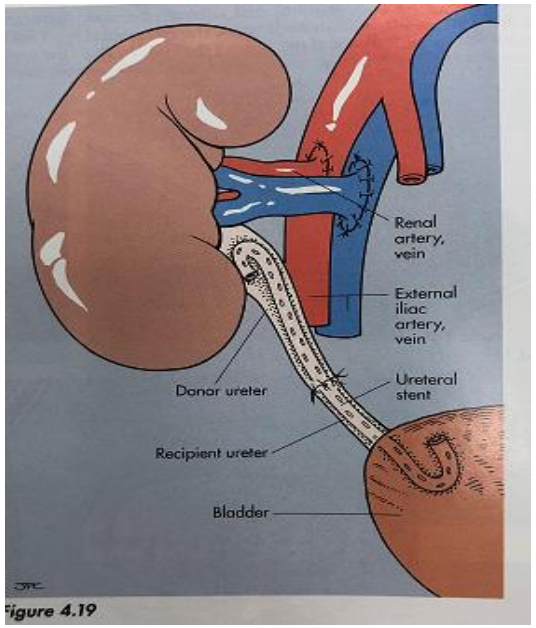


Image courtesy of Starzi, T. E., MD, PHD, Shapiro, R., MD, & Simmons, R. L., MD. (1992). *Atlas of Organ Transplantation*. New York, NY: Gower Medical Publishing.

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Operative Techniques, *Vascular Connections in a Deceased Donor*

Renal Vein

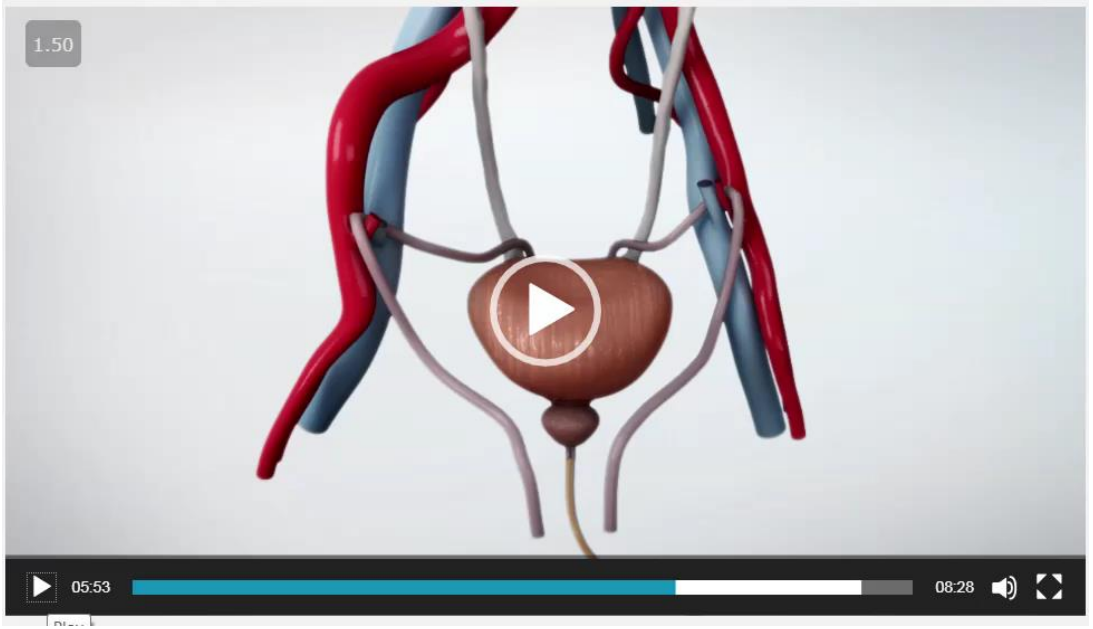
- Sewn to the EIV
- With deceased donor transplants, the donor vena cava may be used as an extension graft for the short renal vein

Renal Artery

- Sewn to the EIA
- In the deceased donor, the donor renal arteries are kept in continuity with a patch of aorta called the **Carrel Patch**. The Carrel patch makes the anastomoses much safer.

Ureter

- Anastomosed to the recipient bladder (1).



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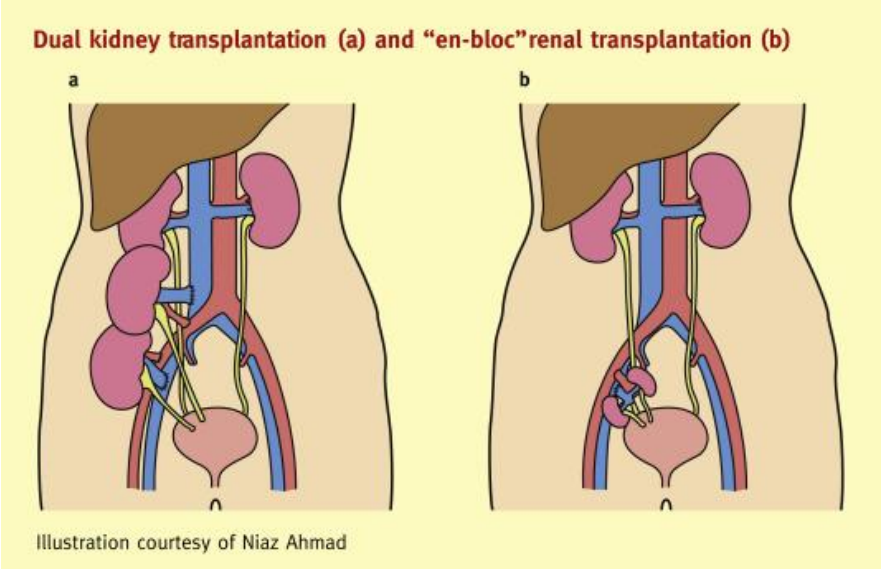
Operative Technique, *Special Considerations*

Dual Kidney Transplantation

- During transplantation of kidneys donated by extremely young children or the elderly, both kidneys are sometimes transplanted into a single recipient as a means to increase kidney mass.

En Block Kidney Transplantation

- Both kidneys from a pediatric patient will be transplanted into an adult.



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Complications s/p Kidney Transplant

1. *Wound Infection*
2. *Lymphocele*
3. *Graft Thrombosis*
4. *Urine Leak*
5. Gastrointestinal
6. Bleeding

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Complications, *Wound Infection*

- Risk of wound infection is **significantly higher** in obese patients

- Now occurring in **< 1%** of patients, this reduced incidence of wound infection s/p kidney transplant is thought to be due to:
  - ❖Thought to be due to use of **perioperative antibiotics.**
  - ❖Patients receiving kidneys are **healthier** than they were 25 years ago.
  - ❖**Lower steroid dosages** used for maintenance and treatment of rejection

- If wound infections do occur, they should be treated with drainage and systemic antibiotics.

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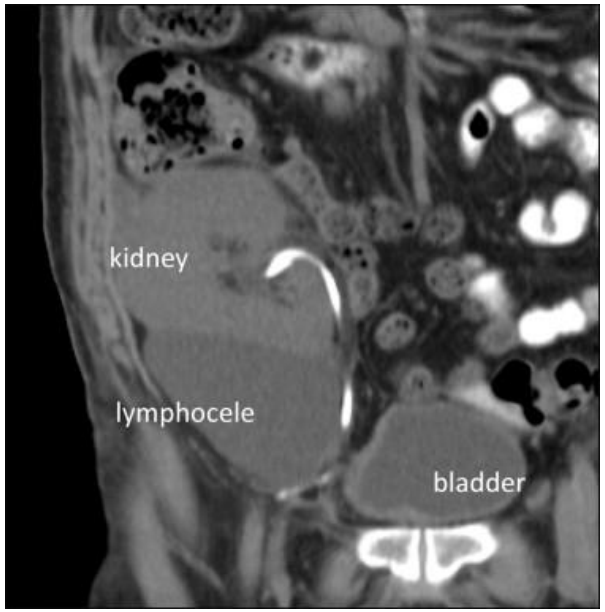
Complications, Lymphocele

Lymphocele - collections of lymph from severed lymphatics that overlie the iliac vessels. Lymphoceles are diagnosed via ultrasound. Obstructed lymphoceles need to be drained.

Lymphoceles may present in the following ways:

- Ureteral obstruction
- DVT/Leg swelling due to compressing the iliac vein
- Bladder incontinence due to compression of the bladder



https://www.google.com/search?q=lymphocele+kidney+transplant&hl=en&authuser=0&rlz=1C1GGRV_enUS751US751&source=lnms&tbm=isch&sa=X&sqi=2&ved=0ahUKEwiR55203vXgAhUVyYsBHRkQCcMQ_AUIDigB&biw=1396&bih=686#imgrc=386Q1qqAccSVXM:

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Complications, *Graft Thrombosis*

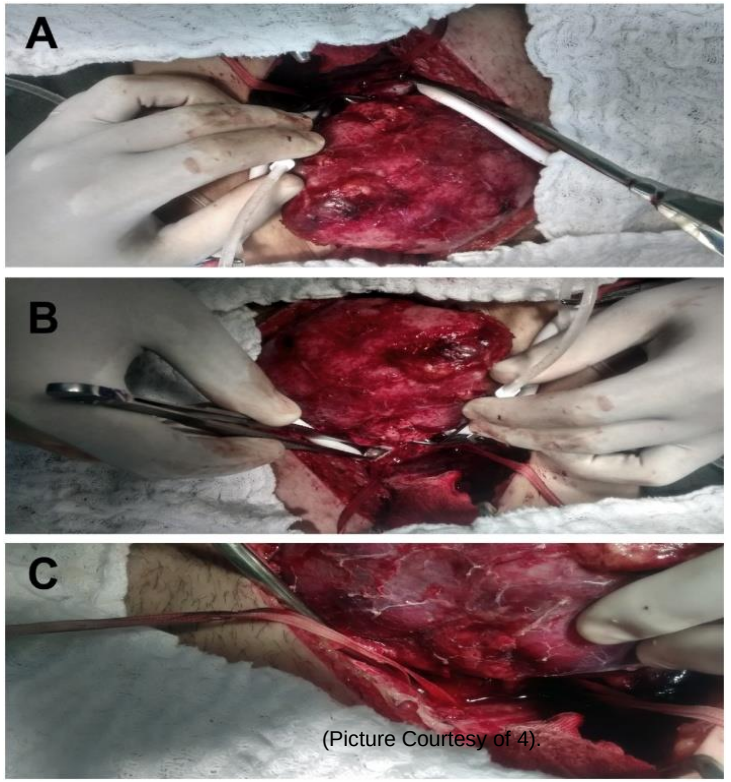
Arterial or Venous Graft Thrombosis- most commonly occurs in the first 2-3 days s/p transplantation, however can occur up to 2 months s/p transplantation.

Presentation: a sudden cessation of urine output and rise in serum creatinine with local pain and graft swelling. However, if patient's native kidneys were a source of urine*, a rise in creatinine might be the only symptom.*

Labs: Thrombocytopenia, Hyperkalemia

Dx: Doppler US or Nuclear flow scan

Treatment: If graft thrombosis is not diagnosed and repaired quickly, the kidney becomes unsalvageable in most cases and graft nephrectomy is performed.



(Picture Courtesy of 4).

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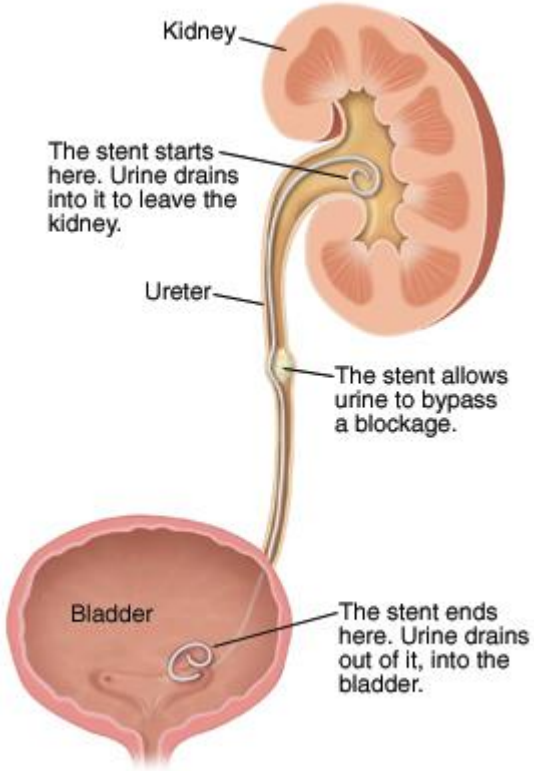
Complications, *Urine Leak*

Urine leak- may occur at the level of the bladder, ureter or the renal cay the first few days after transplantation. May be due to: nonwatertight uretal implanta al slough secondary to disruption of uteteral blood supply. Any leakage from the i **tinine evaluation**.

Presentation: Urine leak may present with agonizing pain, rising plasm nass on US.

Dx: A renal scan will show radioisotope outside of the bladder.

Treatment: Foley Catheter should be placed immediately. If accessible e placed. If due to ureter slough, surgical exploration and repair are required.



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Long Term Complications of Kidney Transplantation

- Rejection
- Infection
- PTLD
- Recurrence of Disease

Kidney-Pancreas Transplantation, *terminology*

SPK- Simultaneous pancreas and kidney transplantation, indicated for select diabetic patients with ESRD.

In the US, more than 75% of pancreas transplants are performed as SPK

The remaining 25% are performed as either:

PAK- Pancreas after kidney transplantation

PTA- Pancreas transplanted alone

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Kidney-Pancreas Transplant History

- December 17, 1966 - first attempt to cure type 1 diabetes by pancreas transplantation was done at the University of Minnesota, in Minneapolis.

- In the mid 80's, pioneers had the idea to renew *the urinary drainage technique of the exocrine secretion of the pancreatic graft.* In parallel, a Swedish research group developed the whole pancreas transplantation technique with **enteric diversion**, which is now considered the **gold standard.**

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Kidney-Pancreas Transplantation, *Benefits*

Survival - Survival for SPK transplant recipients is much better than that of waitlisted patients who continue to receive dialysis [12-14].

In a retrospective review of 351 dialysis patients with type 1 diabetes, at **seven years**, survival rates were **77% among 130 who underwent SPK** transplantation compared with 40% survival rate of 190 who remained on the waiting list (14).

Research shows one-year rates of immunological pancreas graft loss are **1.3% in SPK** and 4-5 % in PTA.

Other potential benefits – In addition to potentially improved survival, pancreas transplantation may decrease morbidity.

Studies have examined the effect of pancreas transplantation on multiple sequelae of diabetes including the following:

- Glucose metabolism
- Lipid metabolism and atherosclerosis
- Nephropathy
- Retinopathy
- Circulation
- Fertility
- Fracture risk

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Kidney-Pancreas Transplantation, *Preservation and Storage*

- The techniques for flushing, cooling and storing the pancreatic graft is very similar to that of kidneys grafts. Most groups use UW solution for flushing and preservation.

- Many centers target cold ischemia time of less than 12 hours, due to risk of graft pancreatitis and graft thrombosis.

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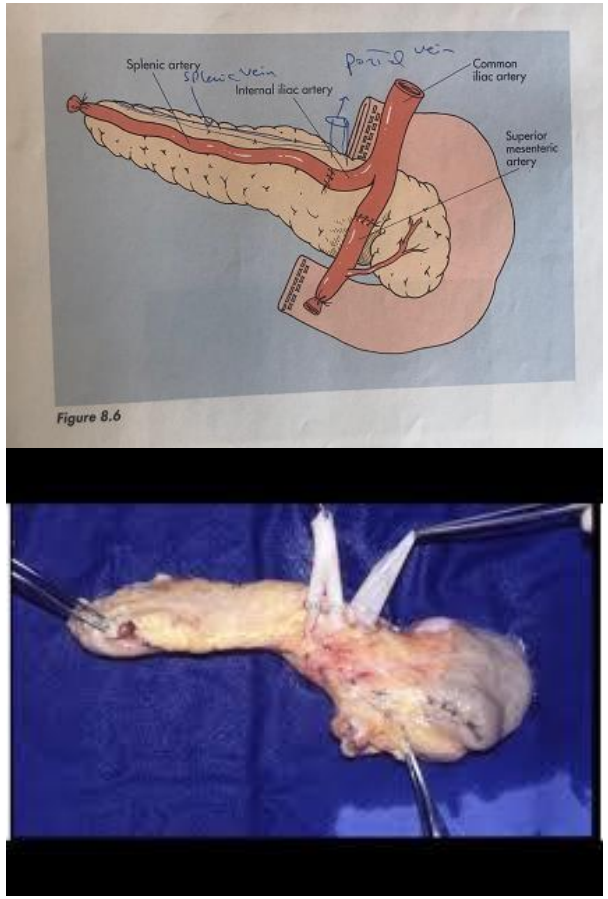
Kidney-Pancreas Transplant, *Operative Technique*

- After careful dissection, the **pancreatoduodenal** graft is removed with an aortic patch containing the celiac and superior mesenteric arteries from the donor.



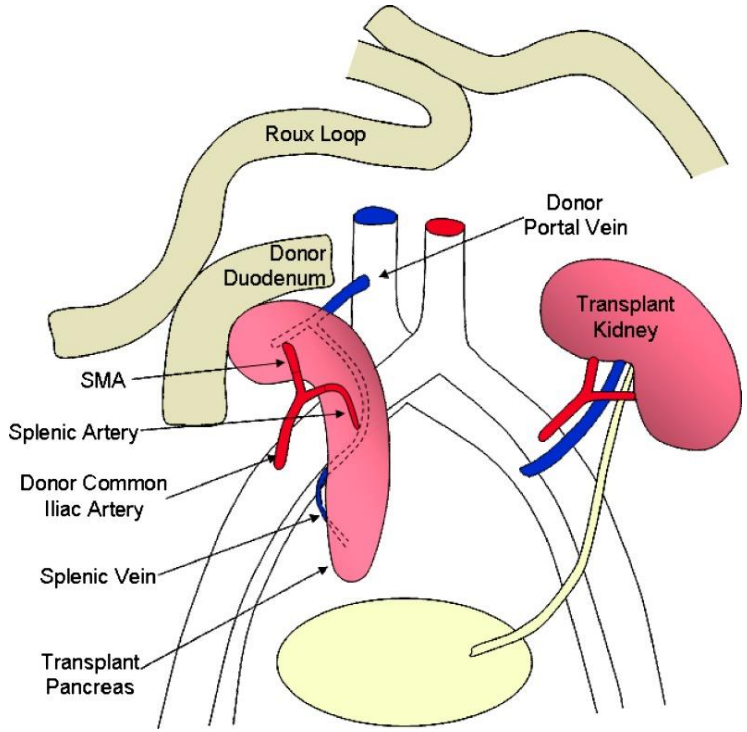
Kidney-Pancreas Transplant, *Operative Technique*

A commonly used technique is to create a vertical midline incision in the recipient, the pancreas is placed intra-peritoneally lying on the right side of the pelvis, while the kidney is placed in the left iliac fossa and is extra peritoneal.

After procurement the dual arterial supply of the pancreas is usually reconstructed with a **Y graft**, derived from donor iliac artery bifurcation.

The donor iliac artery bifurcation is anastomosed to the stumps of the **splenic** and **SMA**, this facilitates implantation.

The venous anastomoses can be accomplished using systemic vs portal drainage.



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Kidney-Pancreas Transplantation

Portal Vs. Systemic Venous Drainage

- Location of venous drainage during pancreas drainage is an important surgical consideration because venous thrombosis is a potentially early complication.

- Location of venous drainage determines where insulin is released into the circulation.

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Kidney-Pancreas Transplantation, *Systemic Drainage*

- Portal vein of pancreas allograft anastomosed to recipient IVC or iliac vein
- Leads to “systemic hyperinsulinemia”
- 82% of SPK and 92% of PAK transplants in the US were performed with systemic venous drainage in 2015 (11).

Image courtesy of:
Tolat PP, Foley WD, Johnson C, Hohenwalter MD, Quiroz FA (2015) Pancreas transplant imaging: how I do it. Radiology 275(1):14–27

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Kidney-Pancreas Transplantation, *Portal Drainage*

- This technique utilizes the recipient's sphlachnic venous system
- Anastomosis between the donor SMV/Portal Vein and Recipient portal vein.
- Leads to "portal hyperinsulinemia" with subsequent "first-pass" hepatic metabolism. This is considered to be more physiologic.

Image courtesy of:
Tolat PP, Foley WD, Johnson C, Hohenwalter MD, Quiroz FA (2015) Pancreas transplant imaging: how I do it. Radiology 275(1):14–27

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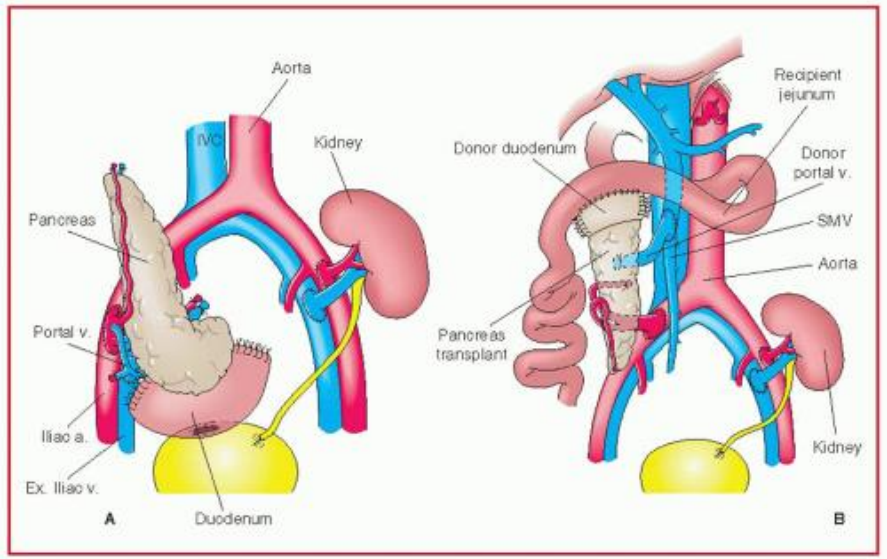
Kidney-Pancreas Transplantation, *Bladder vs. Enteric Exocrine Drainage*

Bladder drainage

Allograft duodenum is anastomosed side-to-side to the recipients bladder

Advantage: urine amylase to monitor for rejection in PAK or PTA

** In SPK serum creatinine is used to monitor for kidney rejection, which is a surrogate for pancreas rejection*



Enteric drainage

Allograft duodenum is to the recipient small bowel, either jejunum or ileum, with or without a diverting Roux-en-Y limb

Advantage: superior in reducing the incidence of metabolic and bladder related complications

* Considered the preferred method

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Kidney-Pancreas Transplantation, *Complications*

1. *Pancreas Failure Secondary to Graft Thrombosis*
2. *Infection*
3. *Post-Transplant Erythrocytosis*
4. Bleeding
5. Duodenal Leak

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Kidney-Pancreas Transplant, *Complications*

The early (first three months) technical failure rate for pancreas recipients in the United States is approximately **5% for SPK** and **7% for PTA** recipients, due primarily to graft thrombosis.

Graft thrombosis is due to the following:

Graft pancreatitis
Hypotension
Reperfusion Injury
Prolonged CIT
Hypercoaguable States

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Kidney-Pancreas Transplant, *Complications*

Infection: The immunosuppressive strategies used in SPK and PAK transplantation expose the patient to an increased risk of bacterial, fungal, and viral infections.

- Cytomegalovirus (CMV) infection is among the most common viruses causing clinically significant infection in SPK recipients
- As in kidney transplant recipients, BK virus may be a significant cause of renal graft loss in SPK recipients (11).
- PTLD – related to EBV cause graft failure and may lead to graft failure.

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Long Term Complications of Kidney-Pancreas Transplantation

- Rejection
- Infection
- PTLD
- Recurrence of Disease

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Questions?

Living Donor Kidney Transplant

Jennie Roggio, RN, BSN

Ely Sebastian, MD

Disclosure

Why Living Kidney Donation

- Recipient gets better quality organ
- Kidney lasts longer 15-20 years
- Immediate kidney function
- Recipient can get preemptive transplant
- Better match if donor is a relative or sibling
- Little waiting time
- Donor gets Psychological benefit from act of altruism.

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Discussing Living Kidney Donation with your Patients

- Encourage patients to tell their story to friends, family, co-workers, church groups, community centers
- Donor champion- someone other than the recipient who can have the difficult conversation to find a live donor
- No waiting time- surgery can be scheduled as soon as donor evaluation is complete.
- Your patient may be concerned for their donors future health. Assure your patient that their donor will have thorough testing and be evaluated by our Donor team. If any findings suggest donation best for their health and well being the donor will **not** be approved for donation.

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Exclusion to Living Kidney Donation

- Age < 18 years
- Hypertension
- Diabetes
- BMI > 35
- High suspicion of donor coercion or financial exchange between donor and recipient
- Creatinine clearance < 80 mL/min by 24 hour urine collection
- Protein excretion > 300mg/day
- Active substance abuse, with the exception of Marijuana
- HIV, Hepatitis C virus, Hepatitis B surface antigen positive
- Mentally incapable of making an informed decision
- Uncontrolled psychiatric illness
- Active malignancy
- Urologic abnormalities/Multiple kidney stones

Living Donor Team Members

- Nephrologist
- Surgeon
- Living Donor Transplant Coordinator
- Living Donor Social Worker
- Independent Living Donor Advocate
- Transplant Dietician
- Transplant Pharmacist

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Independent Living Donor Advocate

The role of the Donor Advocate is to assist the donor by making sure they understand:

- the evaluation process
- the donation surgery with its risks and benefits
- information to help the donor make an informed decision about donation.

The Donor Advocate has detailed knowledge and understanding of the transplantation and the kidney donation process. Their job is to promote and protect the donors interests and to make sure they are making the decision to donate a kidney of their own free will.

The Donor Advocate has no knowledge of the recipient they as well as the donor team are completely separate from the recipient team.

At any time they can call the Donor Advocate to ask questions or talk about any concerns you may have.

Before surgery they will speak again with a Donor Advocate to make sure that all of their questions and concerns have been addressed to their satisfaction.

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Steps to becoming a Living Kidney Donor

- Donor must initiate first contact with the transplant center.
- Donors can call or email the living donor coordinator.
- Recipients should have all donors call. The transplant center can make the decision if they can donate.
- Donors are screened first for any immediate contraindications (diabetes, hypertension, weight)
- Recipients should bring their donors with them to their clinic appointment when possible.

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Living Donor Evaluation

- Informed consent
- Psychosocial evaluation
- Blood and urine studies
- Detailed medical history (including family medical history) and physical examination.
- Surgical evaluation
- Age appropriate cancer screening, cardiac testing and renal imaging.

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Living Donor Evaluation Testing

- ABO/HLA testing
- CDC and Flow T and B cell crossmatch
- 24 hour urine for creatinine clearance and protein
- UA/C&S, LFTs, CBC, BMP, Lipid panel, FBS
- EBV, CMV, Hep B and C, HIV, Quant Gold
- Urine drug screen
- 2 hour oral glucose tolerance test (BMI>28 or family history DM)
- CT Abdomen and pelvis with IV contrast
- Age appropriate cancer screening
- Echocardiogram and stress test
- EKG
- Chest X-ray
- Dermatology clearance

Give a Kidney
one's enough

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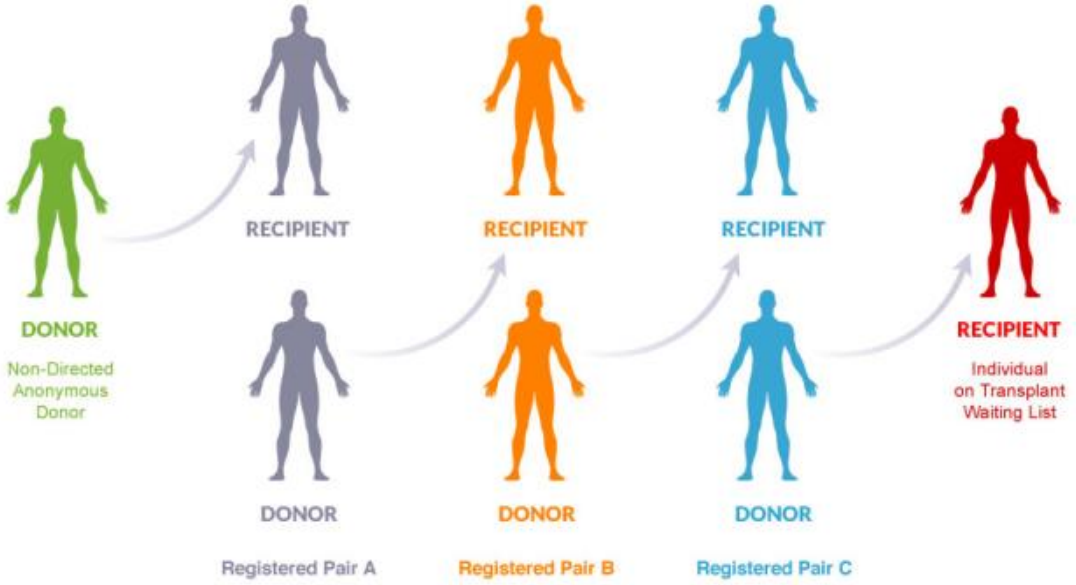
Paired Exchange Option



- ABO incompatible
- Non-directed donor
- Better antigen match
- Better age match
- Paired Exchange can be in a SWAP or Chain format
- Various registries
  - UNOS
  - NKR- National Kidney Registry
  - Internal Swap

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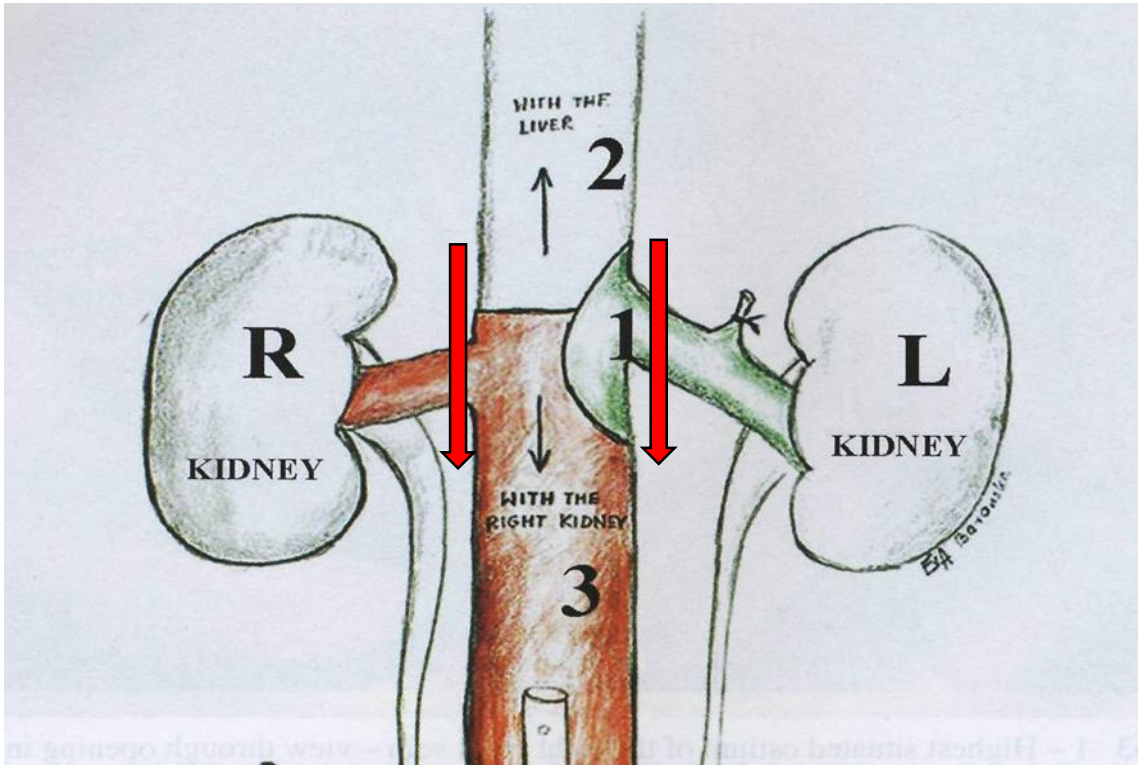
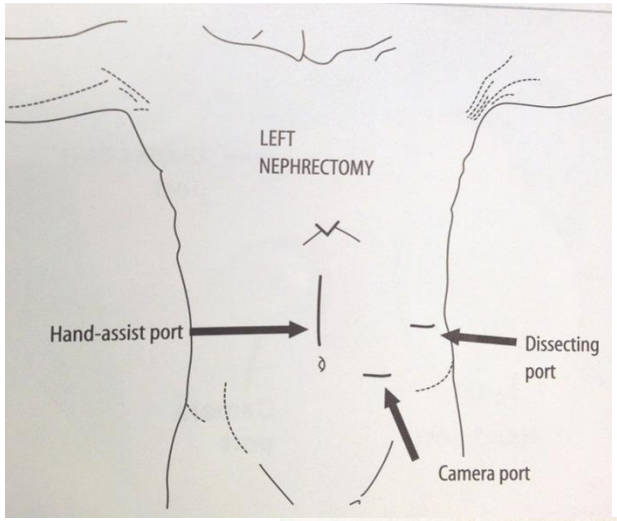
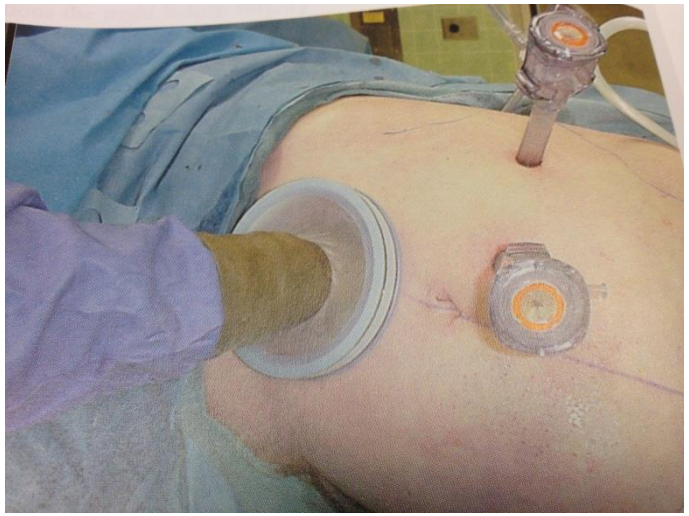
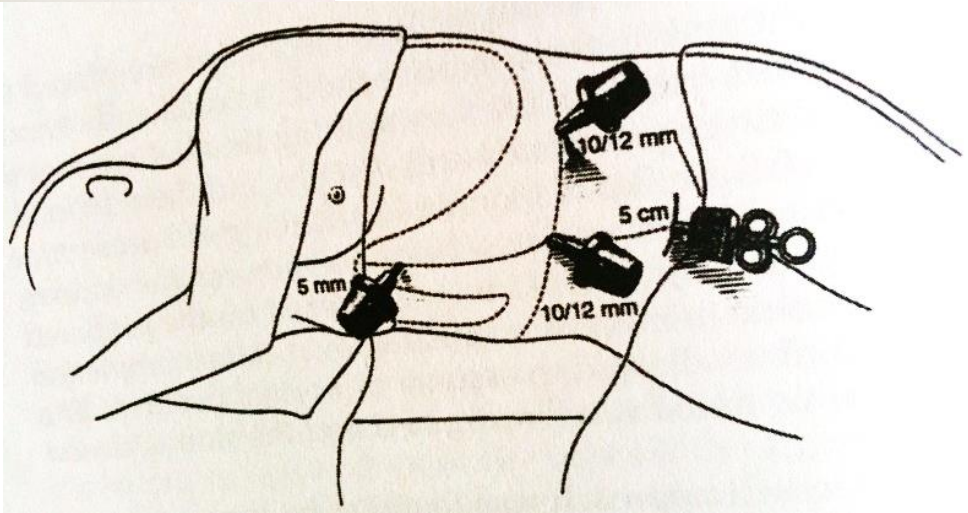
LIVING DONOR



LIVING DONOR







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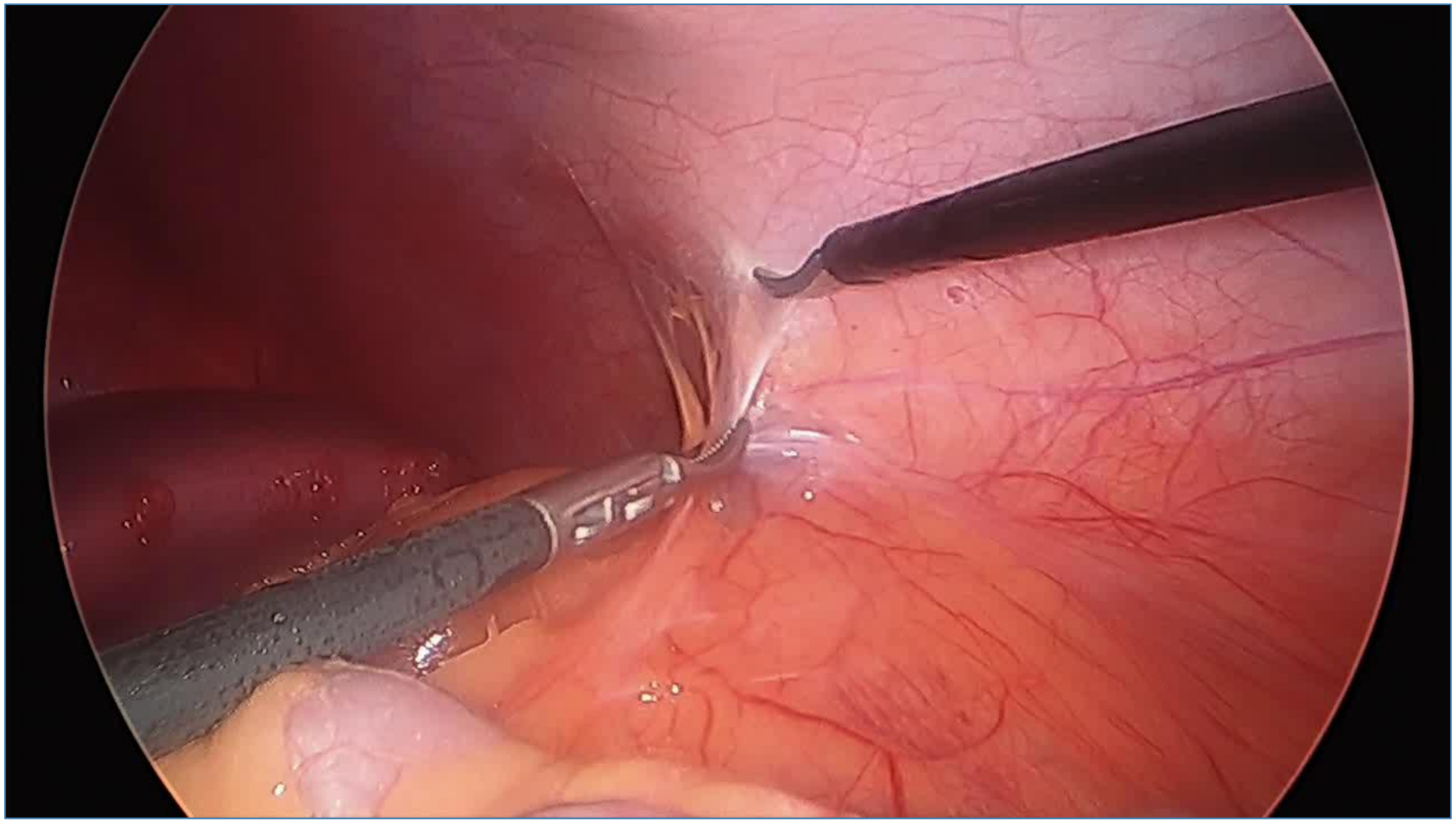
PURE LAPAROSCOPY



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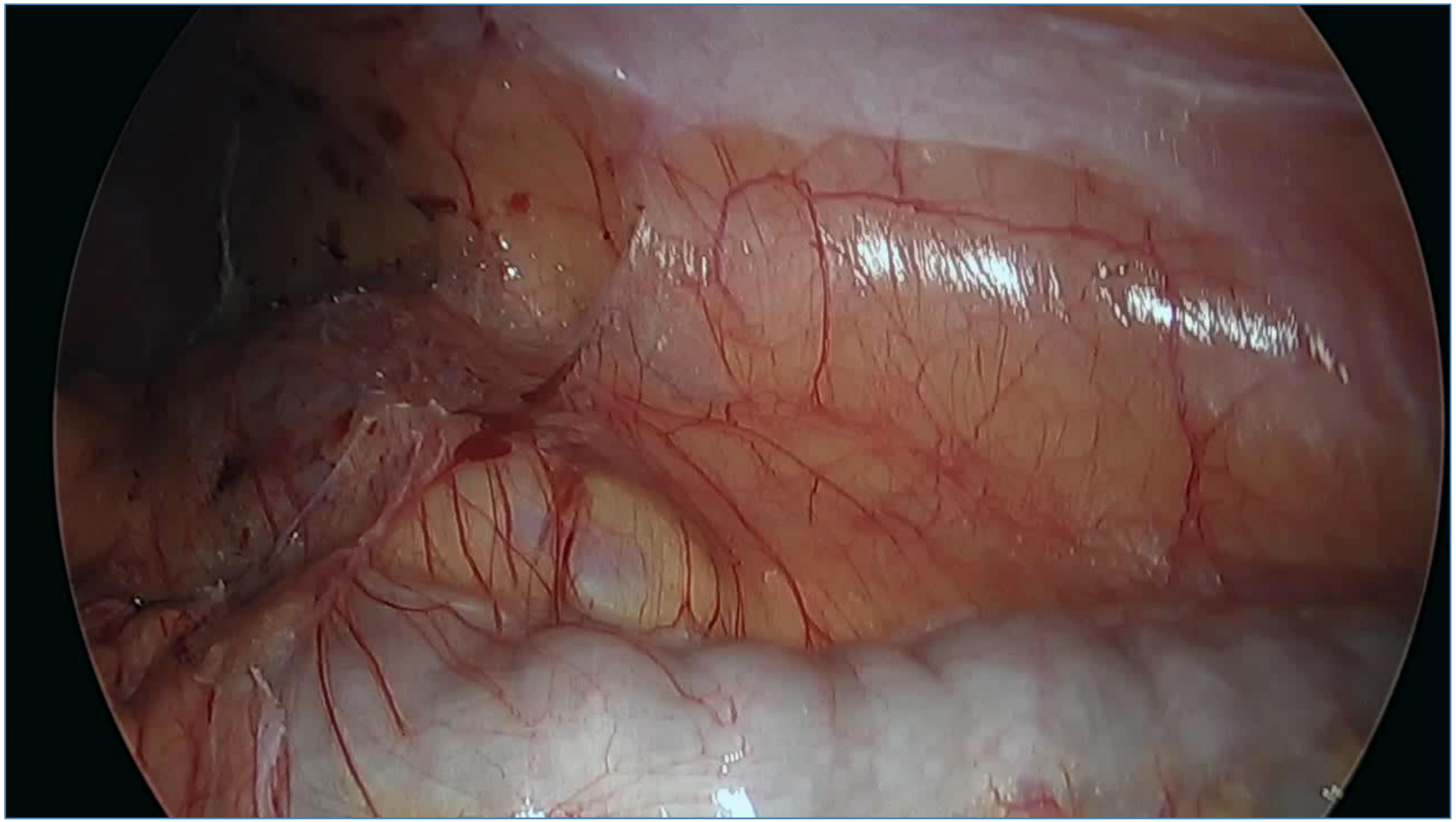
HAND ASSISTED



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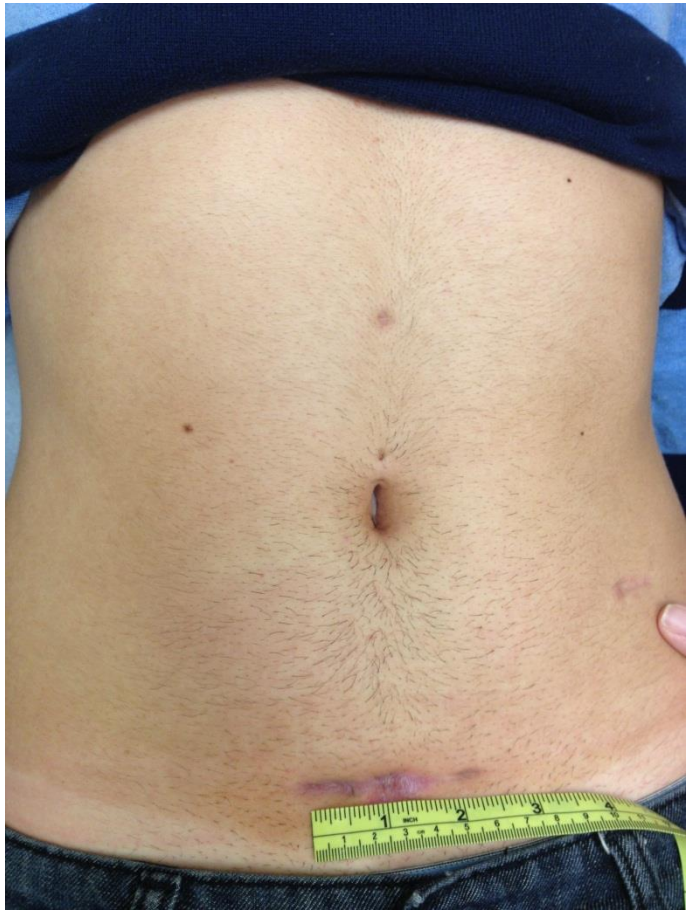

Immediate Complaints

- Pain: PCA, PO narcotics, no pain medications
- Constipation
- Stress

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Questions?

Psychosocial issues in Transplant

Margaret Goodfellow MSW,LSW,NSW-c

Kidney/Pancreas Transplant Social Worker

Disclosure Information

Margaret Goodfellow MSW, LSW,NSW-c
has no financial relationships to disclose.

Objectives:

- For the participant to be able to identify psychosocial factors related to transplant.
- For the participant to be able to identify ways that health professionals can support individual patients in overcoming psychosocial barriers to transplant.
- For the participant to be able to identify the impact that COVID-19 has had on patients at each phase of the transplant process, with the goal of supporting the patient with the process.

What is Transplant?

Pros

- No more dialysis
- Less time spent on medical care?
- Can Improve Quality of Life and longevity
- Easier to travel

Cons

- It’s a treatment not a cure
- Have to take expensive medications for the rest of my life.
- Eligibility for benefits can end after 3 years
- Increased risk of infection

What makes a good dialysis patient?

- Comes to treatments.
- Takes their medications.
- Follows dietary and fluid restrictions and takes phosphorous binders.
- Trust their treatment team and feels comfortable communicating concerns.

What makes a good transplant patient?

- Attends scheduled follow up appointments and has labs drawn as scheduled.
- Takes medications, their medications.
- Is involved in care and is proactive..
- Trusts their treatment team and feels comfortable communicating concerns.

Psychosocial Factors In Transplant
Emotional Impact

- Depression
- Anxiety
- Grief
- Can exacerbate pre-morbid mental health concerns
- Substance Abuse

Depression

- From 20-25% of ESRD patients may suffer from depression.
- May be linked to increased mortality in ESRD patients.
- “Compared with nondepressed patients, the odds are 3 times greater that depressed patients will be noncompliant with medical treatment recommendations.” (DiMatteo, etal)
- Diagnosis can be confounded by medical symptoms of uremia, anemia, etc.

Anxiety

- Under studied in ESRD patients.
- Can be masked by depression, and other physical symptoms.
- Can be linked to non-compliance

Grief

- Loss of health
- Change in roles
- Change in relationships
- Loss of dreams , goals. Not the life hoped for.
- COVID has caused disenfranchised grief in everyone.

Substance Abuse

- Can be a maladaptive way of coping with mental health concerns.
- May have been linked to the cause of Renal failure.
- Can be linked to non-adherence with prescribed treatments.
- Active substance abuse is a contraindication to Kidney Transplant.

Substance Abuse

- Recognizing signs that your patient is using.
- Educating and referring to available resources.
- Recognizing that many patients are coping with multiple stresses, and that self medication can numb the pain of chronic illness and life.
- Be there.

Psychosocial Factors in Transplant

Removing Obstacles

Emotional

- Educating about how physical symptoms can impact emotion
- Normalizing
- Assessing and Referring
- Providing opportunities for patients to support each other
- Helping patients recognize their strengths. How have they dealt with stress/problems in the past?
- Instilling Hope

Mental Health in ESRD

- Untreated mental illness negatively impacts compliance, and is a contraindication for kidney transplant.

- Onset of ESRD can exacerbate pre-existing mental health concerns. Transplant can also exacerbate anxiety, depression, and other mental health concerns.

- Well managed mental health concerns are not a contraindications. Some patients worry that admitting to depression, anxiety, or mental health concerns will rule them out for kidney transplant.

Stress

- Throughout the transplant process patients experience stress, which can impact and exacerbate depression and anxiety.
- Referral phase- performance anxiety, fear of being ruled out, fear of the unknown.
- Listed- Fatigue of waiting, feeling hostage to dialysis and wait list, worry about getting sicker before getting a viable offer.
- Transplant- “They never told me..”, guilt about someone dying, or the sacrifice of a living donor. Adjustment, Regret? Will I experience rejection? What aren’t they telling me?

Psychosocial Factors in Transplant

Financial

- Uncertainty about employment
- Insurance- How will I pay for treatment?
- Planning for the Future-What if I'm not here to provide for my family?
- How will I pay for my medicines when I lose Medicare?

Psychosocial Impact of ESRD
Practical

- Transportation
- Child/Dependent Care while at appointments or receiving treatments
- Household chores

Psychosocial Factors in Transplant

Removing Barriers

Financial

- Education about coverage for Medications and procedure
- Education about Community, State and Federal resources available to assist with pre and post-transplant care
- Educate about FMLA and STDI to protect employment and provide income when out of work at time of transplant, or if there is a complication.
- Educate about accommodations through the Americans with Disabilities Act

Psychosocial Factors in Transplant

Removing Barriers

Practical Concerns

- Refer to resources
- Help patients consider potential avenues for support
- Encourage them to build their team
- Helping patients consider non-traditional supports

Social Support

- Can be associated with less anxiety about practical issues.
- Becomes more of an issue the greater distance a patient lives from the transplant center.
- Supportive listening may be associated with increased cognitive resiliency.
- For some patients the support system may be less apparent. Helping patients consider non-traditional supports such as church, civic groups, extended relatives neighbors.

Psychosocial Factors in Transplant

Health Literacy

- ***Personal Health Literacy*** is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions for themselves and others.

- **Organizational Health Literacy** is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions for themselves and others.

https://www.cdc.gov/healthliteracy/learn/index.html

Psychosocial Factors in Transplant

Personal Health Literacy

- Cognitive/intellectual concerns
- Educational issues
- Cultural/ Language Concerns
- Poverty

Psychosocial Factors In Transplant

Organizational Health Literacy

- Is written material understandable?
- Are interpreters used?
- Are we sensitive to cultural differences?
- Are we sensitive to the reality that accessing health care can be more difficult for poor, immigrant, and minority individuals?

Psychosocial Factors in Transplant

Removing Barriers

Personal Health Literacy

- Assess patient's educational, intellectual, and cognitive status, and present information in an understandable manner.
- Do not assume that an individual understands, just because they are nodding or agreeing. Ask the patient to paraphrase.
- Use relatable analogies to illustrate.
- Do not assume that education is a one-time thing.
- Confirm a patient's ability to read and write.
- Confirm the language that the patient is most comfortable getting complicated information in.

Psychosocial Factors in Transplant

Removing Barriers

Organizational Health Literacy

Five Talking Points on Health Literacy:

- Nine out of 10 adults struggle to understand and use health information when it is unfamiliar, complex or jargon-filled.
- Limited health literacy costs the healthcare system money and results in higher than necessary morbidity and mortality.
- Health literacy can be improved if we practice clear communication strategies and techniques.
- Clear communication means using familiar concepts, words, numbers and images presented in ways that make sense to the people who need the information.
- Testing information with the audience before it is released and asking for feedback are the best ways to know if we are communicating clearly. We need to test and ask for feedback every time information is released to the general public

https://www.cdc.gov/healthliteracy/shareinteract/TellOthers.html

How has COVID impacted patients psychosocially?

Pre-Transplant Phase

- Does patient even want to consider a treatment that is going to further suppress their immune system, while we are still dealing with a pandemic?
- Is the patient vaccine hesitant? How about their immediate family and supports?
- Did patient delay treatment and care for medical conditions, causing them to be sicker as they start the process?
- Education and providing reputable sources for information, that is easily understandable can support patients as they decide to explore transplant, and as they wait to be transplanted.

How has COVID impacted patients psychosocially?

Post Transplant

- Initially fear and concern for immediate safety.
- Support and Direction about work, school, normal activities.
- Currently helping patients consider risk as more services are opened. How to live, as an immunocompromised person, in a world where COVID is a reality.
- Checking in with patients, in person and by phone, to find out how they were coping.
- Providing patients education about the vaccine.

How has COVID impacted patient's psychosocially?

New Transplant Patients

- Initially no visitors
- Concerns about going to the hospital in the midst of a pandemic
- Having an experience different from the one they expected.
- For the team adjusting practices so we could adhere to policy and protocol, and still support patients.
- For some patients COVID presented an opportunity to be transplanted
- Helping patients adjust to a new normal in a crazy world

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Questions?

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Role of the Transplant Designee

Virtua Our Lady of Lourdes Transplant Symposium

November 18, 2021

Quality Insights
Renal Network 3

Disclosure

- I have no actual or potential conflict of interest in relation to this presentation.

Objectives

- Define CMS and ESRD Network Relationship
- CMS regulations for dialysis facility transplant-related responsibilities
- Discuss the role of transplant designee
- Overview of the Transplant Quality Improvement Activity (QIA)
- Resources

End Stage Renal Disease (ESRD) Network

- All Medicare-approved ESRD facilities in a designated geographic area specified by CMS as defined in the Code of Federal Regulations (CFR), at 42 CFR Part 405, Subpart U
  - To promote a system of effective coordination of patient referral and access to resources among dialysis facilities and transplant providers

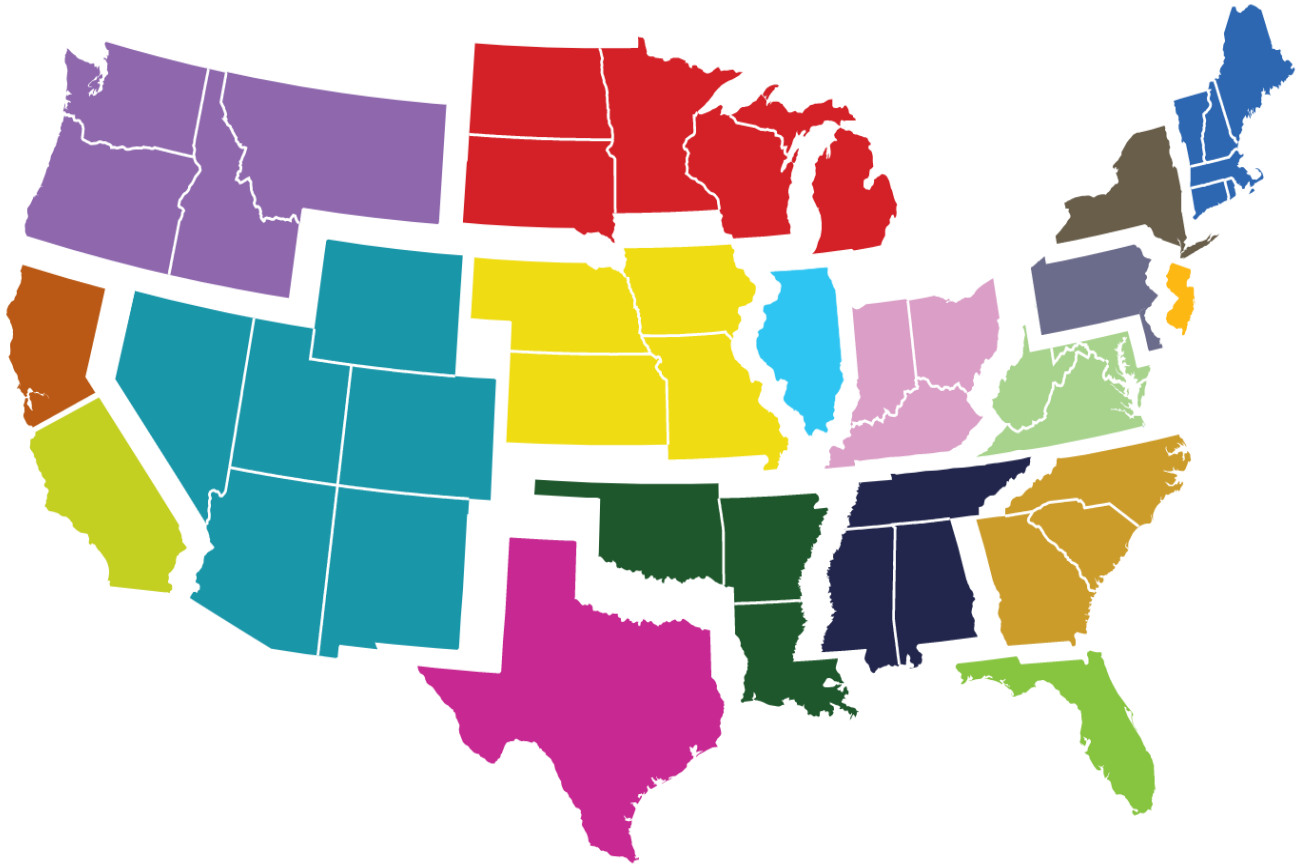
Source: https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations

ESRD Network Organizations

- Dedicated to assisting dialysis facilities and kidney transplant centers in their efforts to provide quality care for patients with ESRD.
- Support achievement of CMS Goals

Source: https://www.cms.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations

ESRD Network Map



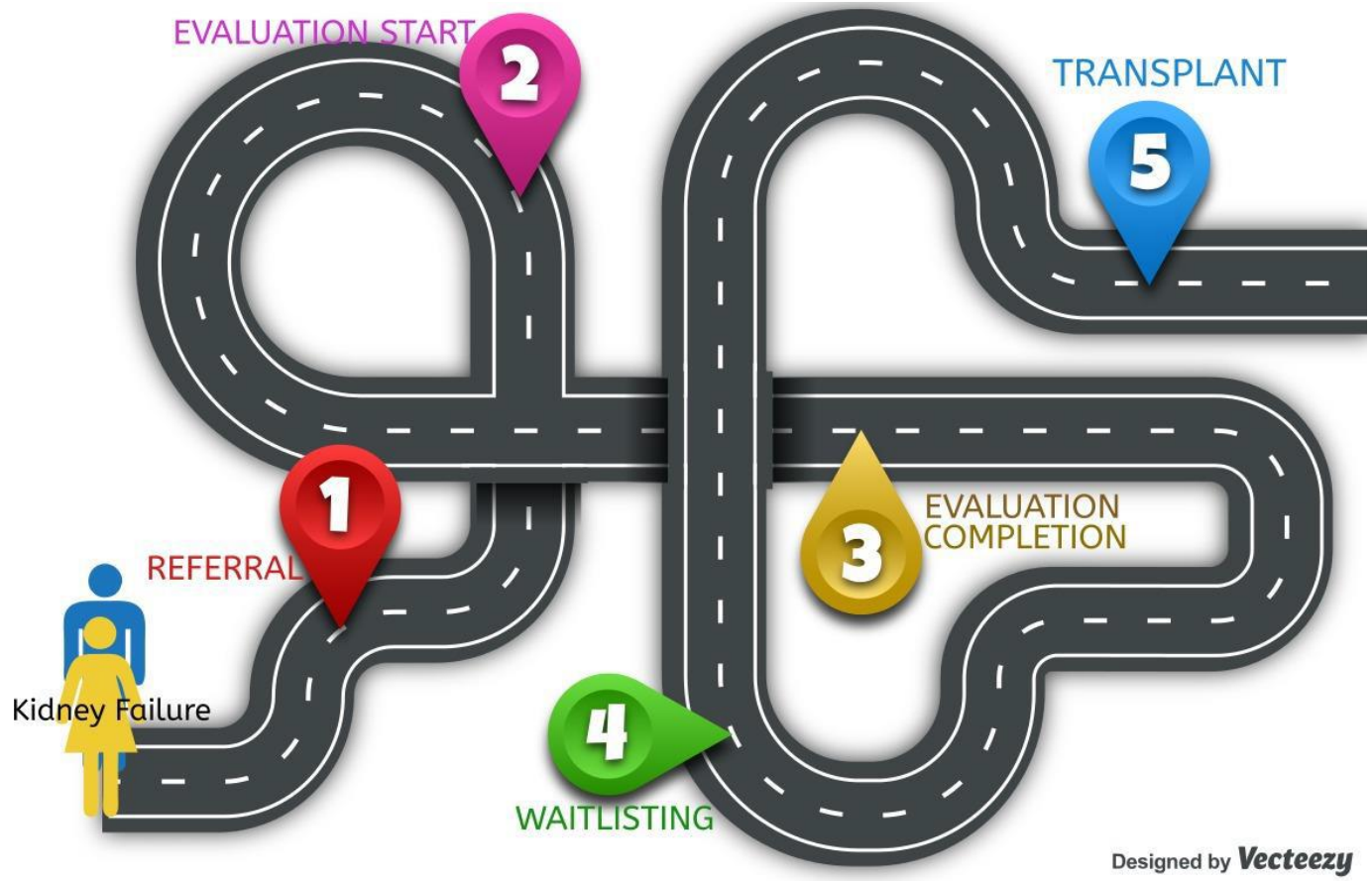
18 Network organizations designated geographically by CMS

QIRN3 – NJ, PR and USVI
QIRN4 – PA and DE

Network Role

- Serving as conveners, organizers, motivators, and change agents;
- Serving as partners in quality improvement with patients, practitioners, healthcare providers, other healthcare organizations, and other stakeholders;
- Securing commitments to create collaborative relationships with other stakeholders and partners;

The Steps to Kidney Transplantation



Source: ESRD Forum Kidney Transplant Toolkit

CMS Regulations on Transplantation

Source: ESRD Interpretive Guidance

Federal Regulations V458 and V562

The patient has the right to-

- Be informed about all treatment modalities and settings, including but not limited to, transplantation…

- d) Standard: Patient education and training. …in home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types

Federal Regulations V513 (10)

- Evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s).

- If the patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient's medical record.

Federal Regulations V554

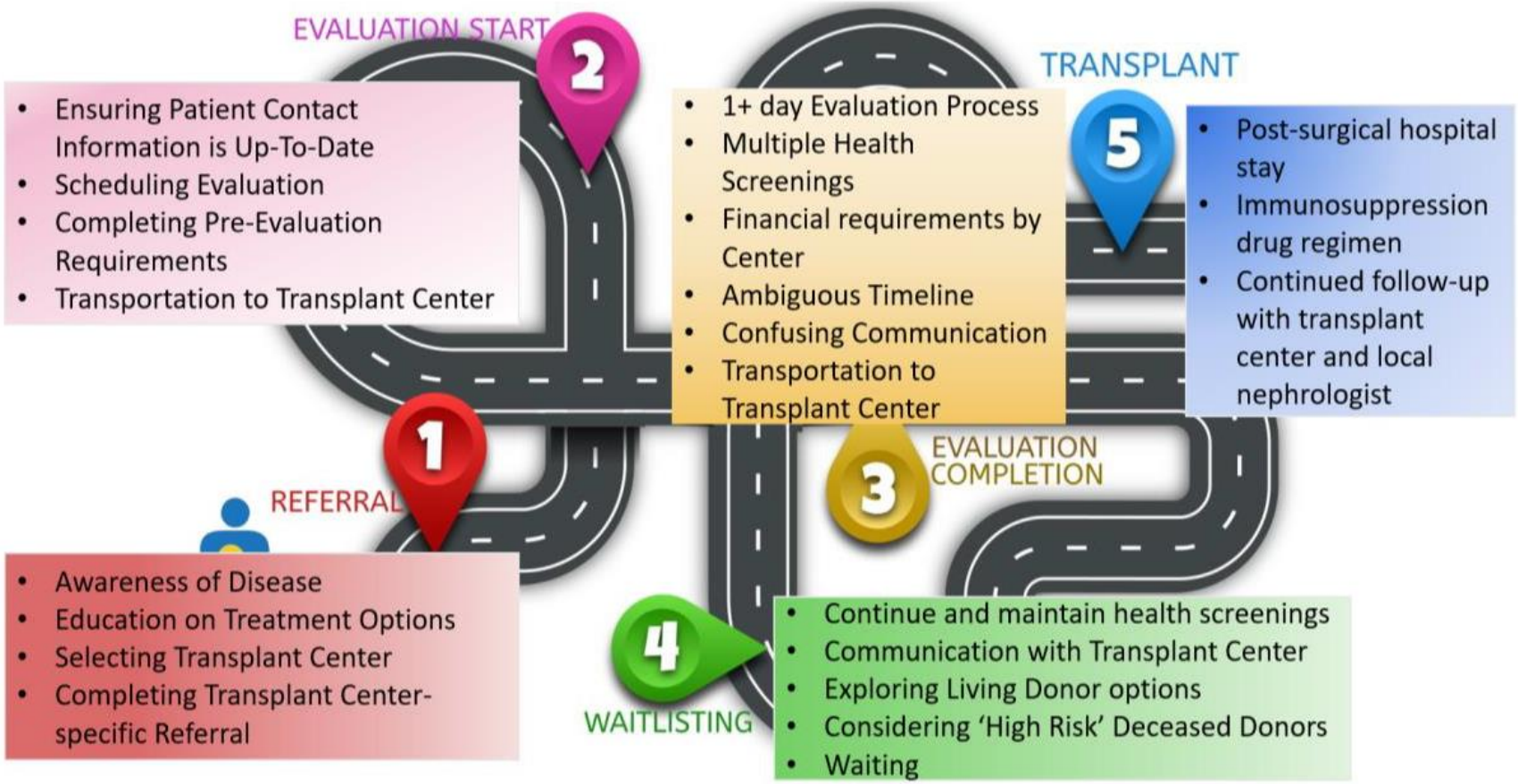
- Transplantation status. When the patient is a transplant referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient's plan of care must include documentation of the:
  - (A) Plan for transplantation
  - (B) Patient's decision
  - (C) Reason(s) for the patient's nonreferral as a transplantation candidate

Federal Regulations V561 (c)

Standard: Transplantation referral tracking. The interdisciplinary team must—

- (1) Track the results of each kidney transplant center referral;
- (2) Monitor the status of any facility patients who are on the transplant wait list;
- (3) Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status

The Road to Kidney Transplantation

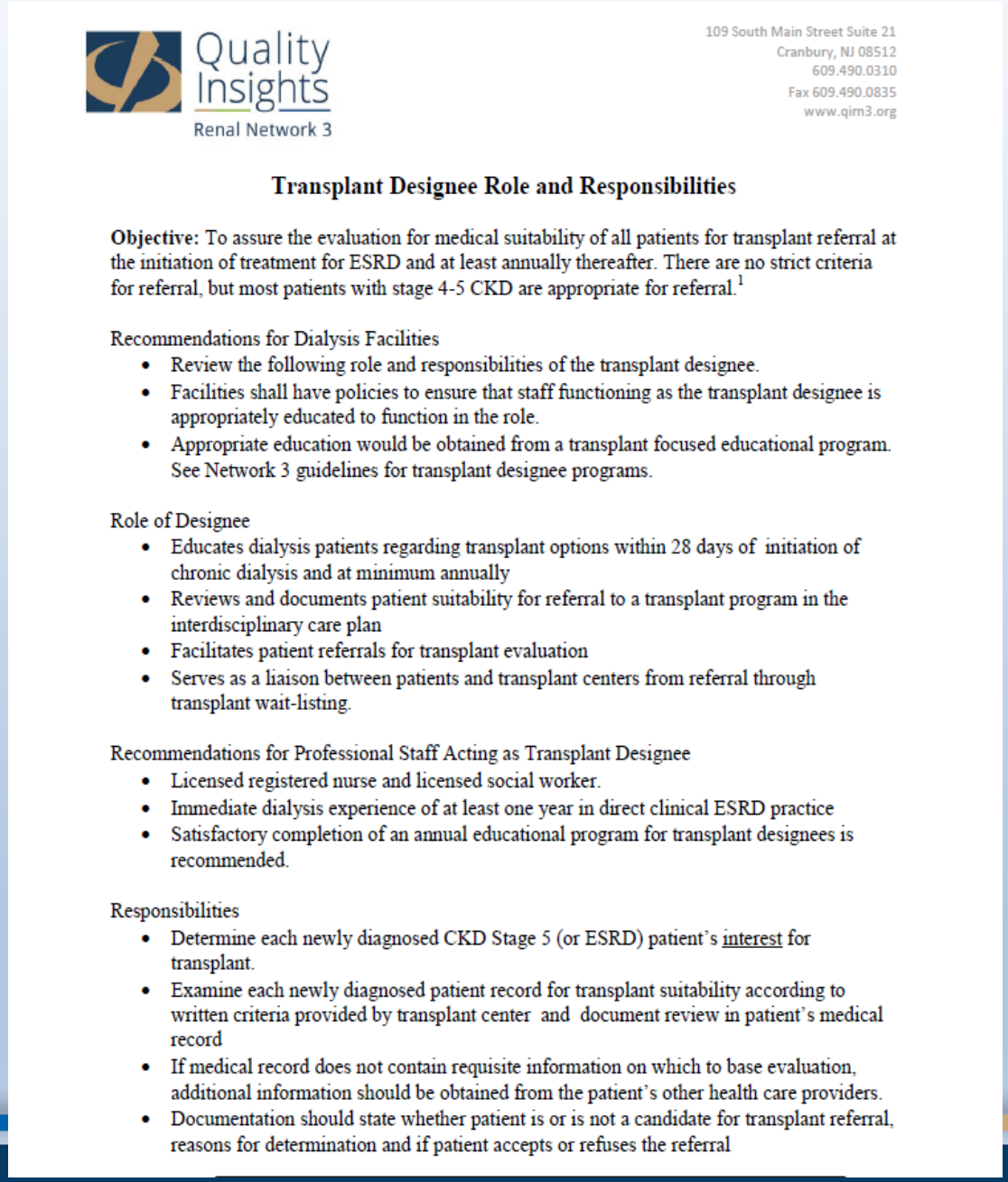


Source: ESRD Forum Kidney Transplant Toolkit

New Jersey (NJ) State Specific Regulation

- New Jersey State: N.J.A.C. Title 8, Chapter 43A, Standards for Licensure of Ambulatory Care Facilities
  - 8:43A-24.13 Patient care plan, (b) Within one calendar month of initiation of dialysis treatment at the facility, a written plan of care shall be developed for each ambulatory dialysis patient by a multidisciplinary team consisting of at least, a nephrologist, a **transplant surgeon or designee**, a registered professional nurse, a registered dietitian, and a licensed social worker. The plan of care shall specify observable and measurable goals and expected patient outcomes. The multidisciplinary team shall analyze patient outcomes on a regular basis to assess the patient's progress and evaluate current and future treatment modalities and modify the plan as necessary.

Transplant Designee Role and Responsibilities Document



Quality Insights
Renal Network 3

109 South Main Street Suite 21
Cranbury, NJ 08512
609.490.0310
Fax 609.490.0835
www.qirn3.org

Transplant Designee Role and Responsibilities

Objective: To assure the evaluation for medical suitability of all patients for transplant referral at the initiation of treatment for ESRD and at least annually thereafter. There are no strict criteria for referral, but most patients with stage 4-5 CKD are appropriate for referral.[1]

Recommendations for Dialysis Facilities

- Review the following role and responsibilities of the transplant designee.
- Facilities shall have policies to ensure that staff functioning as the transplant designee is appropriately educated to function in the role.
- Appropriate education would be obtained from a transplant focused educational program. See Network 3 guidelines for transplant designee programs.

Role of Designee

- Educates dialysis patients regarding transplant options within 28 days of initiation of chronic dialysis and at minimum annually
- Reviews and documents patient suitability for referral to a transplant program in the interdisciplinary care plan
- Facilitates patient referrals for transplant evaluation
- Serves as a liaison between patients and transplant centers from referral through transplant wait-listing.

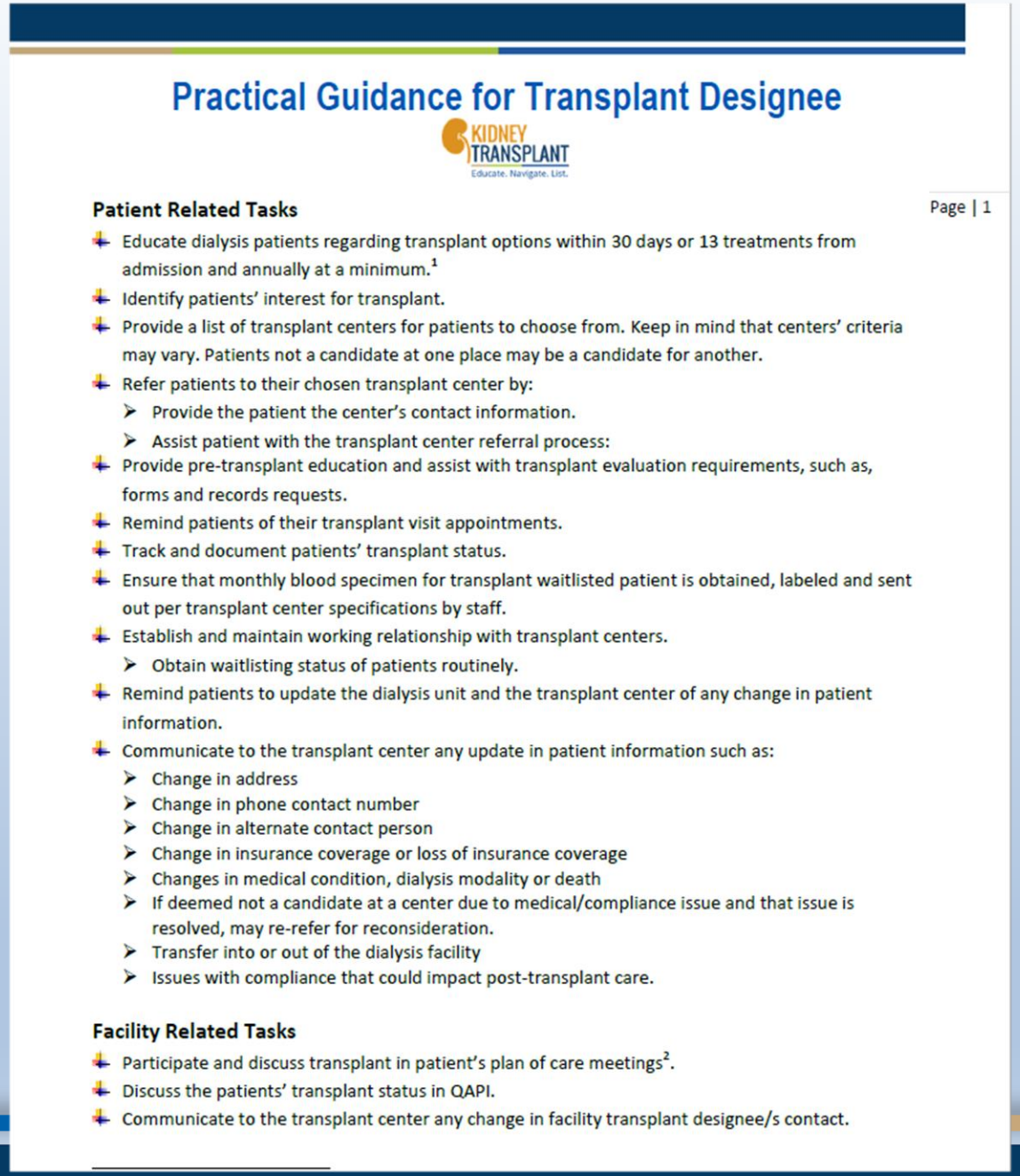
Recommendations for Professional Staff Acting as Transplant Designee

- Licensed registered nurse and licensed social worker.
- Immediate dialysis experience of at least one year in direct clinical ESRD practice
- Satisfactory completion of an annual educational program for transplant designees is recommended.

Responsibilities

- Determine each newly diagnosed CKD Stage 5 (or ESRD) patient's interest for transplant.
- Examine each newly diagnosed patient record for transplant suitability according to written criteria provided by transplant center and document review in patient's medical record
- If medical record does not contain requisite information on which to base evaluation, additional information should be obtained from the patient's other health care providers.
- Documentation should state whether patient is or is not a candidate for transplant referral, reasons for determination and if patient accepts or refuses the referral

Practical Guidance for Transplant Designee



Practical Guidance for Transplant Designee

KIDNEY TRANSPLANT
Educate. Navigate. List.

Patient Related Tasks

- Educate dialysis patients regarding transplant options within 30 days or 13 treatments from admission and annually at a minimum.[1]
- Identify patients' interest for transplant.
- Provide a list of transplant centers for patients to choose from. Keep in mind that centers' criteria may vary. Patients not a candidate at one place may be a candidate for another.
- Refer patients to their chosen transplant center by:
  - Provide the patient the center's contact information.
  - Assist patient with the transplant center referral process:
- Provide pre-transplant education and assist with transplant evaluation requirements, such as, forms and records requests.
- Remind patients of their transplant visit appointments.
- Track and document patients' transplant status.
- Ensure that monthly blood specimen for transplant waitlisted patient is obtained, labeled and sent out per transplant center specifications by staff.
- Establish and maintain working relationship with transplant centers.
  - Obtain waitlisting status of patients routinely.
- Remind patients to update the dialysis unit and the transplant center of any change in patient information.
- Communicate to the transplant center any update in patient information such as:
  - Change in address
  - Change in phone contact number
  - Change in alternate contact person
  - Change in insurance coverage or loss of insurance coverage
  - Changes in medical condition, dialysis modality or death
  - If deemed not a candidate at a center due to medical/compliance issue and that issue is resolved, may re-refer for reconsideration.
  - Transfer into or out of the dialysis facility
  - Issues with compliance that could impact post-transplant care.

Facility Related Tasks

- Participate and discuss transplant in patient's plan of care meetings[2].
- Discuss the patients' transplant status in QAPI.
- Communicate to the transplant center any change in facility transplant designee/s contact.

Transplant Quality Improvement Activity (QIA)

- Improve Education and Access to Empower Patient Choice of Transplant
  - Nationwide effort to improve kidney care
  - In 2019, the U.S. Department of Health and Human Services launched the Advancing American Kidney Health Initiative (AAKH)
  - AAKH has goal of 80% of new patients in 2025 begin dialysis at home or receive a pre-emptive kidney transplant

Goal (1)

- Increase the number of patients *added to a kidney transplant waiting list*

Facility activities that can influence this goal:

- Identify and educate patients
- Refer interested patients to transplant center
- Facilitate evaluation toward waitlisting
- Assist in addressing barriers that impede waitlisting

Goal (2)

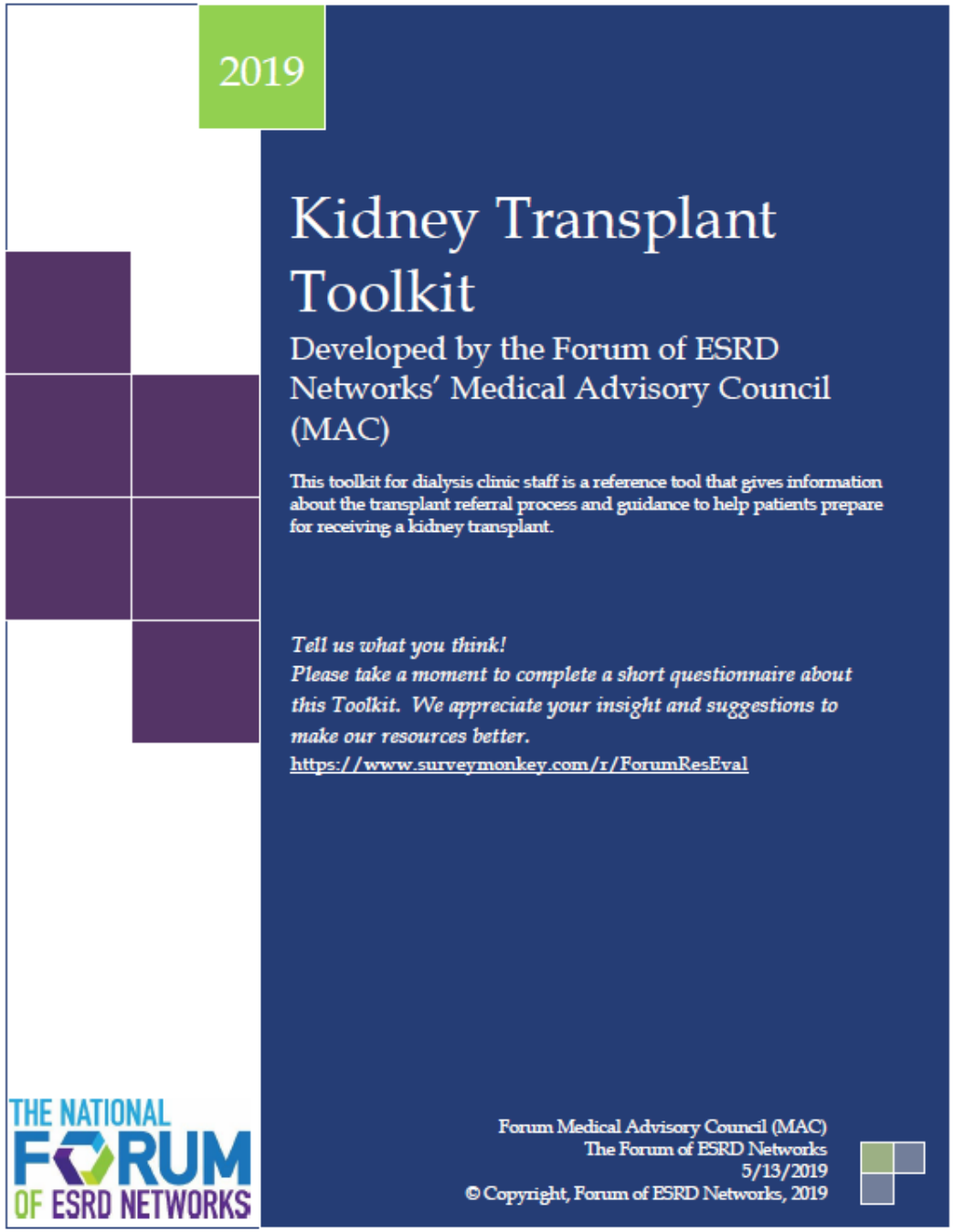
- Increase in the number of patients *receiving a kidney transplant*

Facility activities that can influence this goal:

- Keep actively waitlisted patients healthy
- Monthly lab work is properly obtained, labeled and shipped timely
- Ensure patient contact information updated
- Identify reasons for inactivation and help address modifiable barriers
- Educate on High Kidney Donor Profile Index (KDPI) kidneys
- Promote living donation

Resources

[ESRD Form Kidney Transplant Toolkit]



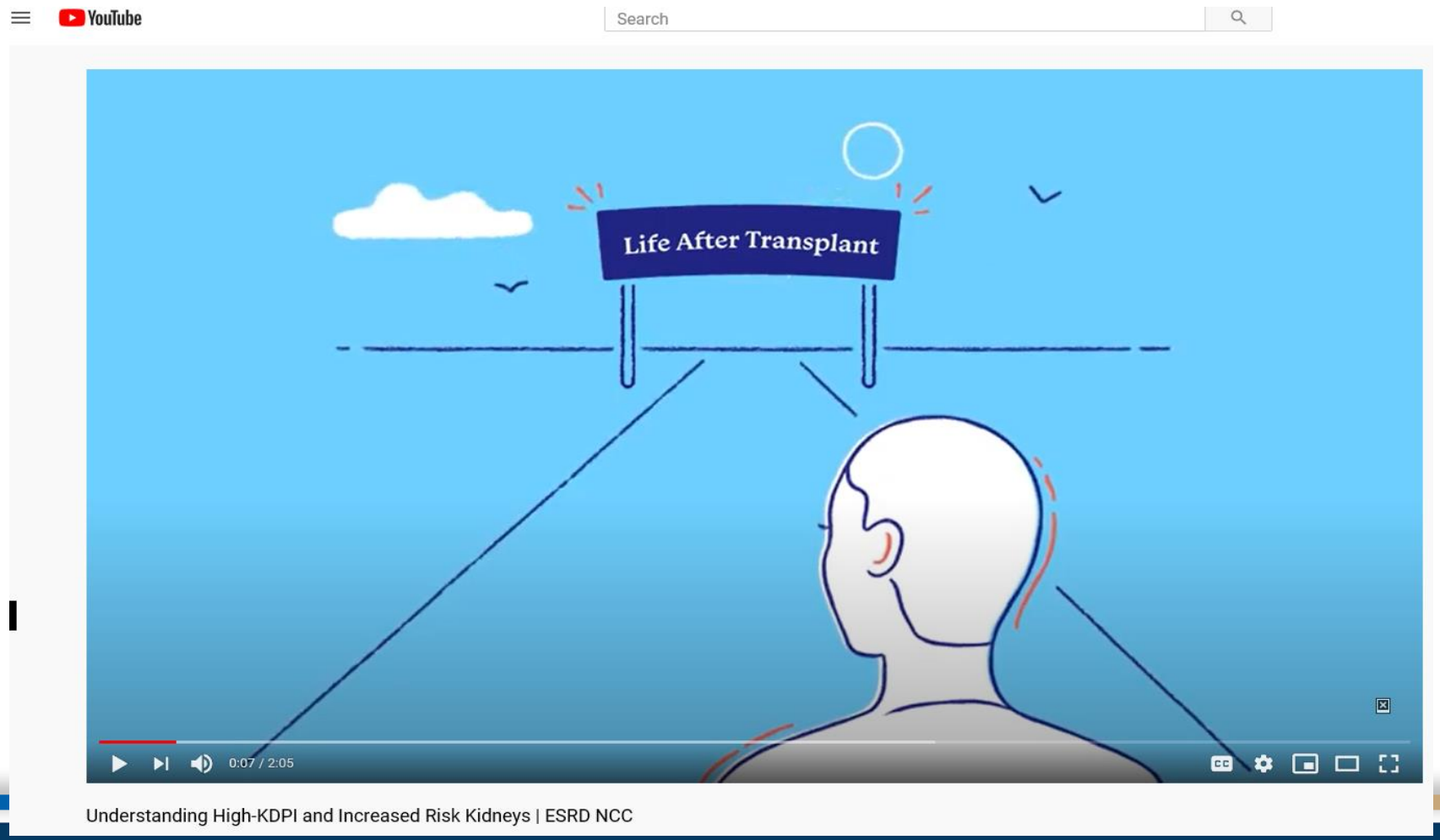
Kidney Transplant Hub

Your Kidney Transplant Journey Starts Here

Have you been diagnosed with kidney failure? Your diagnosis presents a challenge, but also the opportunity to return to a healthy life. This guide contains resources for you to consider transplant as the preferred treatment option for kidney failure.

Choose Transplant | Get on a Waitlist | Stay Healthy on the Waitlist | Receive a Kidney Sooner | Connect with the Community | Enjoy Life After Transplant

High-Kidney Donor Profile Index (KDPI) Patient Education Video



Kidney and Transplant Online Resources

Explore Transplant	www.exploretransplant.org
UNOS Kidney Transplant Learning Center	www.transplantliving.org/kidney/about-the-kidney-transplant-learning-center/
Ascent to Transplant	www.ascenttotransplant.org
iChoose Kidney	www.ichoosekidney.emory.edu
My Transplant Coach	https://mytransplantcoach.org/#/
U.S. Dept. of Health & Human Services	www.organdonor.gov

Living Donor Websites

Alliance for Paired Donation	www.paireddonation.org
Gift of Life Donor Program	https://www.donors1.org/
Living Donors Online	www.livingdonorsonline.org
Living Donation Storytelling Library	www.explorelivingdonation.org
National Kidney Registry	www.kidneyregistry.org
NJ Sharing Network	https://www.njsharingnetwork.org/living-donation
Renewal	www.life-renewal.org
UNOS Kidney Paired Donation Pilot Program	https://unos.org/donation/kidney-paired-donation/

Financial Resources for a Transplant or Living Donation

American Living Organ Donor Network	www.helplivingdonorssavelives.org
American Kidney Fund	www.kidneyfund.org
American Transplant Foundation	www.americantransplantfoundation.org
National Foundation for Transplants	www.transplants.org
National Living Donor Assistance Center	https://www.livingdonorassistance.org/Home/default.aspx

Network Transplant QIA Contact

- QIRN3 (NJ, PR, USVI)
  - Virna de la Cruz, Quality Improvement Coordinator
    - vdelacruz@qualityinsights.org

Questions?

Thank you!

Monthly Sample Collections

Jennie Roggio, BSN, RN

Disclosure

Specimen Collection

- Submit 1 blood tube, once per month, preferably in the beginning of the month
- Draw the blood prior to dialysis treatment, and label it **immediately** upon collection
- Use a 10 mL or 6mL **plain red top tube**
- Fill the tubes at least ¾ full

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Labeling Requirements

1. Patient's Full Name
2. DOB
3. Last 4 Digits of SSN
4. Date of Collection
5. Phlebotomist's Initials

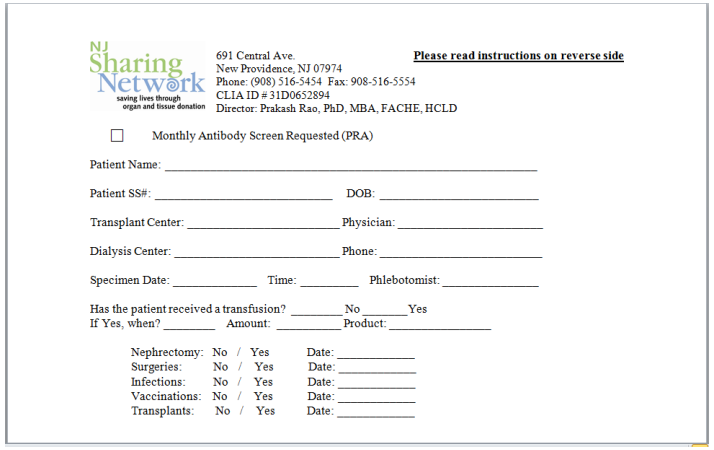
**** Print legibly

Name: ____John Doe _____
DOB: 01/02/03_ SSN: _xxx-xx-1234_
Date Drawn: _03/01/2015_____
Phlebotomist Initials: _AA_____

Virtua Health

Cytotoxic Requisition

- Please submit a cytotoxic requisition for each sample. This helps us confirm the information on the tubes in case there's typos with the name or draw date.
- List any sensitizing events, including but not limited to transfusions, pregnancies, infections, and/or vaccinations.



NJ Sharing Network
saving lives through organ and tissue donation

691 Central Ave.
New Providence, NJ 07974
Phone: (908) 516-5454 Fax: 908-516-5554
CLIA ID # 31D0652894
Director: Prakash Rao, PhD, MBA, FACHE, HCLD

Please read instructions on reverse side

☐ Monthly Antibody Screen Requested (PRA)

Patient Name: _____

Patient SS#: _____ DOB: _____

Transplant Center: _____ Physician: _____

Dialysis Center: _____ Phone: _____

Specimen Date: _____ Time: _____ Phlebotomist: _____

Has the patient received a transfusion? _____ No _____ Yes
If Yes, when? _____ Amount: _____ Product: _____

Nephrectomy:	No / Yes	Date:	_____
Surgeries:	No / Yes	Date:	_____
Infections:	No / Yes	Date:	_____
Vaccinations:	No / Yes	Date:	_____
Transplants:	No / Yes	Date:	_____

Virtua Health

Waste No Time

- Ship the specimen on the day of collection or within 24hrs (at room temperature)
- Do not refrigerate the specimen
- Do not centrifuge the specimen (or separate the serum)

“Canisters”

- Our shipping kits, or “canisters”, consist of a lidded plastic cylinder that goes inside a larger cardboard container.
- Use all the pieces provided in the kit, including the lids on both ends. Do not separate the units or send separately.
- Use these kits to ship specimens only to our lab.
- Available in small or large:

    Large holds up to 5 tubes

    Small holds 1-2 tubes

Virtua Health

Packaging: Step 1

- Wrap each blood tube individually with a zip-lock bag or biohazard specimen bag.
- Do not use rubber bands.
- We recommend using an absorbent material.

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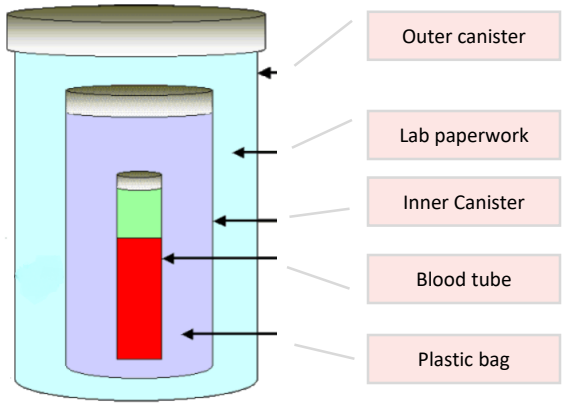
Packaging: Step 2

- Place the individually wrapped tubes inside the inner canister
- Do not over pack the canister with too many tubes
- Place the inner canister inside the larger cardboard canister, and place the paperwork in between the two containers
- Be sure to secure the inner and outer lids of the containers



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Packaging Regulations

- All specimens shipped to our lab must be packaged in compliance with your shipping carrier (USPS, FedEx, or UPS).
- Any pathogenic blood specimens categorized as Category B Biological/Infectious Substances, must be packaged in compliance to regulatory ground and air transport agencies (familiarize yourself with these regulations, and check carrier‘s website).
- Always seal all shipping bags and boxes!

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Shipping & Delivery Options

- Specimens can be shipped to our lab via:

- The transplant hospital may provide **pre-paid shipping labels**.
- We encourage you to use expedited delivery methods to prevent hemolysis (especially during extreme temperatures)

Last but not Least

- Ship all transplant samples to:
- **NJ Sharing Network**
- **Transplant Laboratory**
- **691 Central Avenue**
- **New Providence, NJ 07974**

- To request canisters:
- http://www.njsharingnetwork.org/lab
- NJ Sharing Network Transplant Laboratory (908) 516-5454

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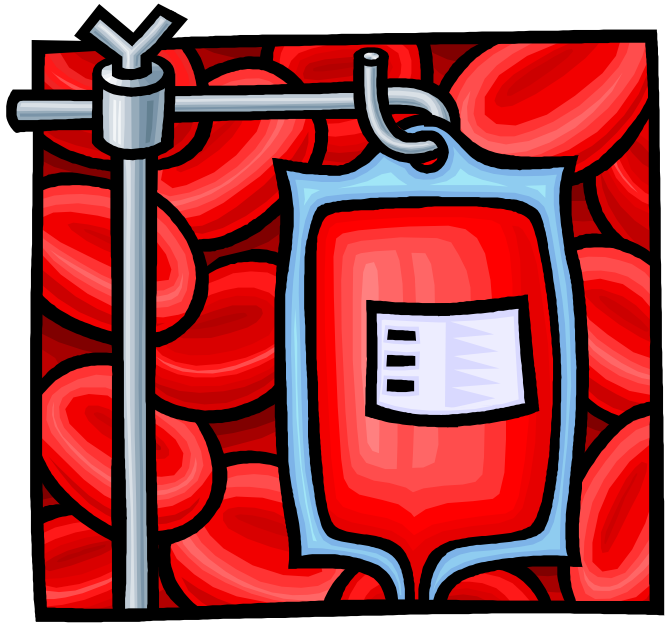
Sensitizing Events

- Transfusion
- Pregnancy
- Infection
- Previous Transplant
- Transplant Nephrectomy
- High PRA can delay transplantation



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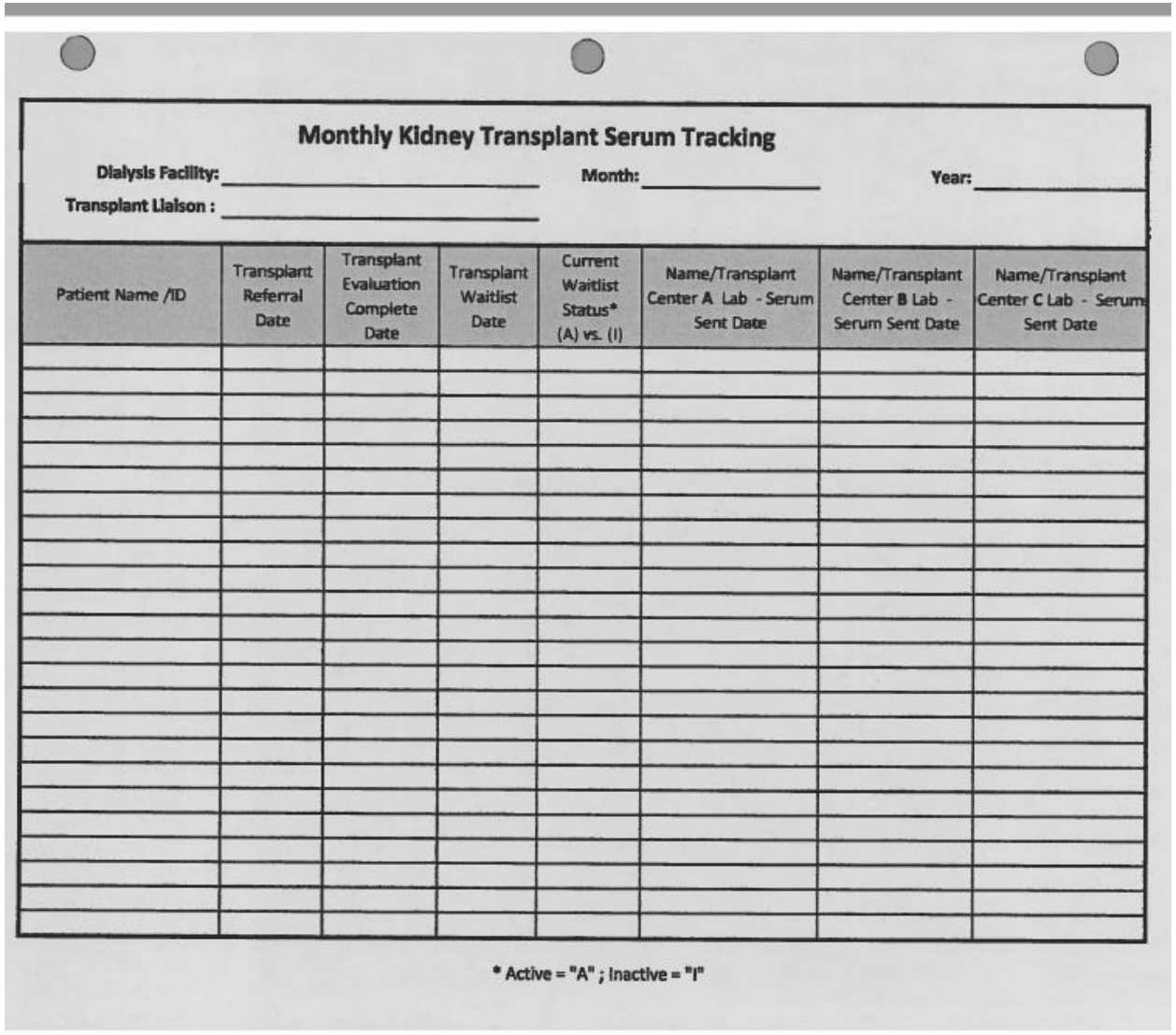
Monthly Samples

- Must be sent to NJSN, or transplant lab every 30 days
- Must be labeled and packaged properly
- Must be accompanied by paperwork
- Some patients may require 2 red-top tubes to be sent monthly
- Samples are preserved for crossmatching should a patient be called for transplant. In addition, sample is also tested every 90 days for the presence of antibodies
- If a patient has a sensitizing event, needs to be accurately noted on accompanied paperwork with sample and antibody levels checked sooner than 90 day period
- Failure of patient having updated sample at lab may influence their opportunity to be transplanted

Tracking Tool Monthly Samples



Monthly Kidney Transplant Serum Tracking

Dialysis Facility: _____ **Month:** _____ **Year:** _____

Transplant Liaison : _____

Patient Name /ID	Transplant Referral Date	Transplant Evaluation Complete Date	Transplant Waitlist Date	Current Waitlist Status* (A) vs. (I)	Name/Transplant Center A Lab - Serum Sent Date	Name/Transplant Center B Lab - Serum Sent Date	Name/Transplant Center C Lab - Serum Sent Date

* Active = "A" ; Inactive = "I"

Virtua Health

Questions?

The New Organ Allocation System and the Process of Dual Listing

Janine Vallen, RN, MSN, CCTN, APN-C

Nasser Youssef, MD

Disclosure

Organ Allocation

- Multifactorial
- Varies per donor organ being offered (there is no permanent numerical order position)
- Is often unpredictable. Patients active on the waiting list can be called for transplant at anytime.
- There is a mismatch between supply and demand. Allocation rules and policies have changed over the years

National Transplant Waiting List:

National Data

Home » Data » View Data Reports » National Data » Overall by Organ

Overall by Organ
Current U.S. Waiting List
For Format = Portrait

Based on OPTN data as of November 1, 2021

Change Report (Optional) :
Count

Candidates Go

		All Organs	Kidney	Liver	Pancreas	Kidney / Pancreas
Candidates		106,686	90,279	11,696	845	1,793

OPTN November 2, 2021

Virtua Health

UNOS

Transplant Solutions Technology Data Policy Community Resources News

and living donors in 2020. Here, see the percentage change from between 2019 and 2020 by organ type.

Kidney	↓ 2.5%	2020: **22,817**	2019: **23,401**
Liver	↑ 0.1%	2020: **8,906**	2019: **8,896**
Heart	↑ 3%	2020: **3,658**	2019: **3,552**
Lung	↓ 6.4%	2020: **2,539**	2019: **2,714**
Pancreas	↓ 5.6%	2020: **135**	2019: **143**
Kidney-pancreas	↓ 5.2%	2020: **827**	2019: **872**

Number of Transplants 2019 - 2020

OPTN November 2, 2021

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How long does a candidate wait?

- Is a combination of total points a candidate is assigned and then applied to various classifications of prioritization in a match run

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Allocation for Kidney/Pancreas

- Base on criteria of allocation within 250NM or National level.
- Classifications of donor/recipient/match

- Points

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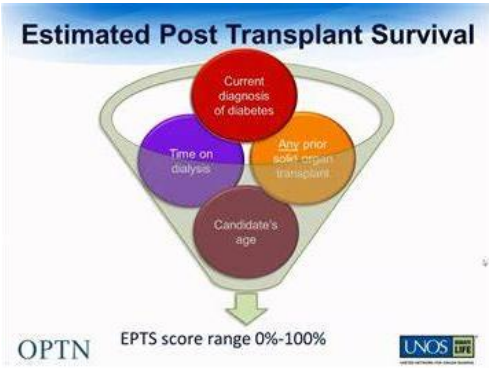
Classifications and Ranking of Match

- EPTS scoring
- Deceased donor scoring (KDPI <20, 20-34, 35-85)

Longevity matching

- Medical urgency status
- Blood type allocation
- Prior living donor status
- Prior liver transplant recipient (within preceding 12 months)
- Highly sensitized candidate (98, 99, 100%)
- 0 Ag MM- ABDR

EPTS Scoring based on:



- Candidate time on dialysis
- Whether or not the candidate has a current diagnosis of diabetes
- Whether or not the candidate has had any prior solid organ transplant
- Candidate age

**Expected post transplant survival time- utilized in longevity matching. For scoring <20%, patients expected to live the longest are allocated kidneys expected to last the longest.

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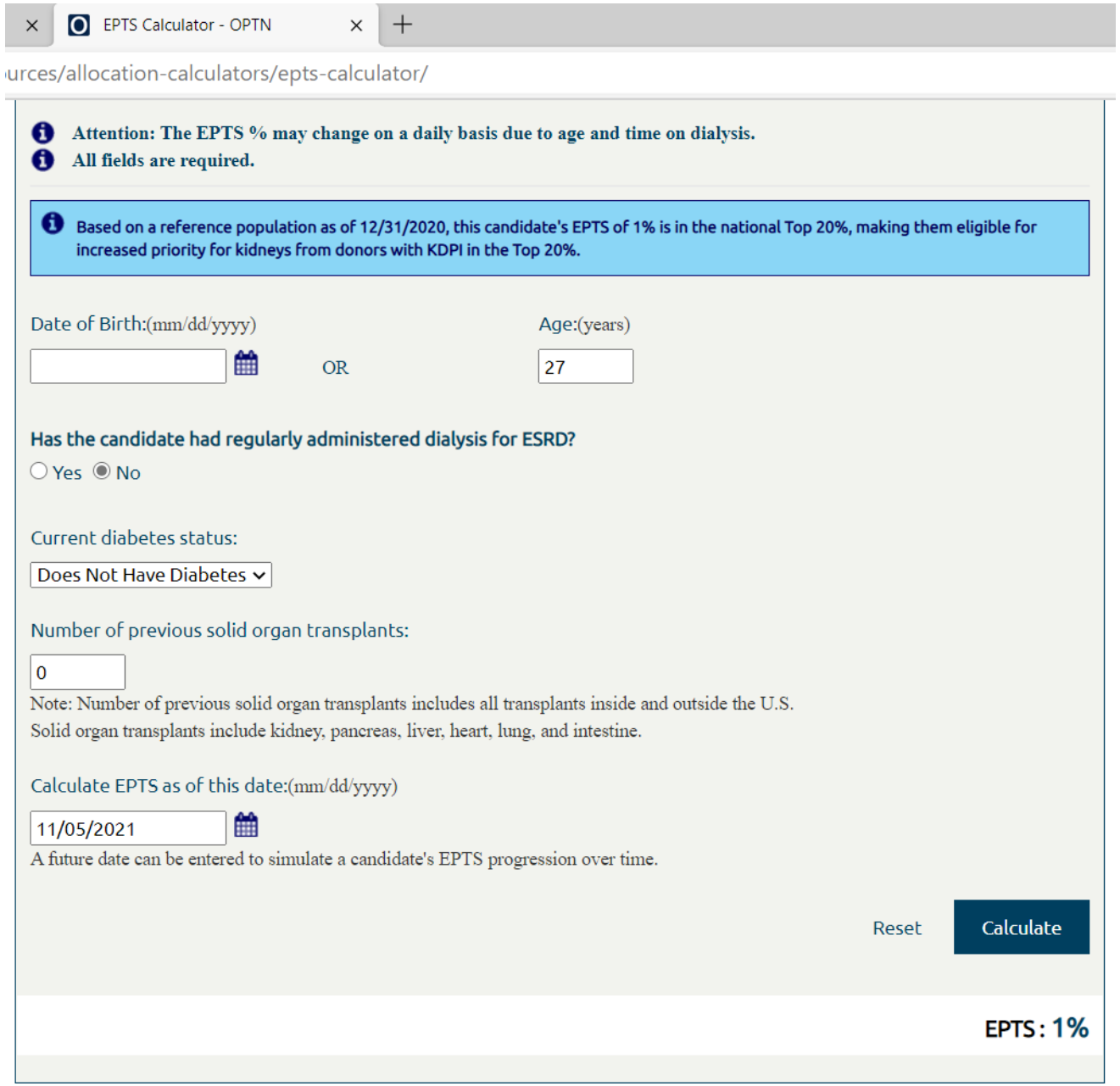

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KDRI- Kidney Donor Risk Assessment/KDPI

- Age
- Ethnicity
- Creatinine
- History of Hypertension
- History of Diabetes
- Cause of Death
- Height
- Weight
- Donor type
- HCV status

***Scoring 0-100. The lower the score, the better predicted quality

Medically Urgent Status

- First, the candidate must have exhausted, or has a contraindication to, all dialysis access via all of the following methods:
  - Vascular access in the upper left extremity
  - Vascular access in the upper right extremity
  - Vascular access in the lower left extremity
  - Vascular access in the lower right extremity
  - Peritoneal access in the abdomen
- After exhaustion or contraindication to all dialysis via the methods listed above, the candidate must also either have exhausted dialysis, be currently dialyzed, or have a contraindication to dialysis via one of the following methods:
  - Transhepatic IVC Catheter
  - Translumbar IVC Catheter
  - Other method of dialysis (must specify)

Kidney Allocation for Donors with KDPI 35% - 85% MATCH RESULTS

DCD Donor Match

OPO Contact Number : (215) 557-8095

Note: These data are provided for organ allocation and monitoring purposes and are subject to applicable privacy and confidentiality regulations. Use of these data for any other purpose is not san
Review Board (IRB) before using these data for any other purpose.

View all Provisional Acceptances>> Show distance

Match ID: 1367853 KI # Per Page: 100 Hide empty classifications

View only candidates listed at NJLL-TX1

250NM, 0-ABDR mismatch, 100% CPRA, blood type identical or permissible
250NM, 100% CPRA, blood type identical or permissible
Nation, 0-ABDR mismatch, 100% CPRA, blood type identical or permissible
Nation, 100% CPRA, blood type identical or permissible
250NM, Prior living donor, blood type identical or permissible
250NM, Medically Urgent
250NM, 0-ABDR mismatch, 99% CPRA, blood type identical or permissible
250NM, 99% CPRA, blood type identical or permissible
250NM, 0-ABDR mismatch, 98% CPRA, blood type identical or permissible
250NM, 98% CPRA, blood type identical or permissible
250NM, 0-ABDR mismatch, blood type identical
Nation, 0-ABDR mismatch, 80%-100% CPRA, blood type identical
Nation, 0-ABDR mismatch, 21%-79% CPRA, less than 18 years old, blood type identical
Nation, 0-ABDR mismatch, 0%-20% CPRA, less than 18 years old, blood type identical
Nation, 0-ABDR mismatch, 21%-79% CPRA, blood type identical
250NM, 0-ABDR mismatch, blood type B (for blood type O donor only)
Nation, 0-ABDR mismatch, 80%-100% CPRA, blood type B (for blood type O donor only)
Nation, 0-ABDR mismatch, 21%-79% CPRA, less than 18 years old, blood type B (for blood type O donor only)
Nation, 0-ABDR mismatch, 0%-20% CPRA, less than 18 years old, blood type B (for blood type O donor only)
Nation, 0-ABDR mismatch, 21%-79% CPRA, blood type B (for blood type O donor only)
250NM, 0-ABDR mismatch, blood type permissible
Nation, 0-ABDR mismatch, 80%-100% CPRA, blood type permissible
Nation, 0-ABDR mismatch, 21%-79% CPRA, less than 18 years old, blood type permissible
Nation, 0-ABDR mismatch, 0%-20% CPRA, less than 18 years old, blood type permissible
Nation, 0-ABDR mismatch, 21%-79% CPRA, blood type permissible

250NM, Prior liver recipients meeting qualifying criteria (according to policy), blood type identical or permissible

Seq#	Center	Name	SSN	DOB	Age	ABO	CPRA	Score	Mismatch		
									A	B	DR
1	****_***	***, ***	***-**-****	*****	54	B	0	1.88	1	2	1

250NM, blood type B (for blood type A2/A2B donor only)

250NM, blood type identical or permissible

Seq#	Center	Name	SSN	DOB	Age	ABO	CPRA	Score	Mismatch		
									A	B	DR

Sample of match run in UNET

UNET

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Kidney Candidate Point Scoring:

- Points, 1 per 356 days of date registered or qualified
- cPRA points, at least 20%
- Degree of match points (0DR MM, 1DRMM)
- Prior living donor points
- New – Proximity points up to 2 max within 250 NM circle, up to 4 points outside of circle

Allocation Score/Points

8.3 Kidney Allocation Score

Candidates receive an allocation score according to the total of all points assigned in *Table 8-1.*

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points
Meets the qualifying criteria described in *Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	*See Table 8-3: Points for Allocation of Kidneys based on Proximity to Donor Hospital*

If the candidate's CPRA score is:	Then the candidate receives this many points:
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

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Example of patient points

- 27 year old female, blood group O, non diabetic, no previous history of transplant on dialysis for just over 4 years with cPRA 72%. EPTS score 1%

Calculated Score:

- Dialysis time 4.06
- cPRA + 1.09

- Total Points/Score 5.15

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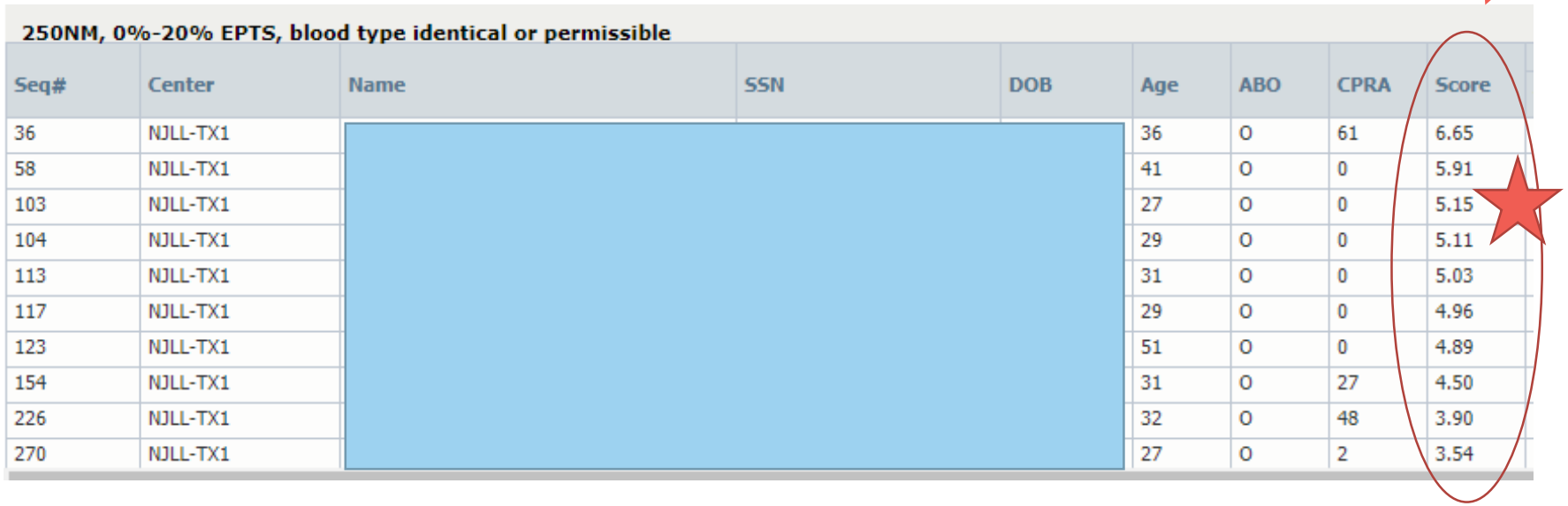
Distance/category/ranking

Sum of points/score



250NM, 0%-20% EPTS, blood type identical or permissible

Seq#	Center	Name	SSN	DOB	Age	ABO	CPRA	Score
36	NJLL-TX1				36	O	61	6.65
58	NJLL-TX1				41	O	0	5.91
103	NJLL-TX1				27	O	0	5.15
104	NJLL-TX1				29	O	0	5.11
113	NJLL-TX1				31	O	0	5.03
117	NJLL-TX1				29	O	0	4.96
123	NJLL-TX1				51	O	0	4.89
154	NJLL-TX1				31	O	27	4.50
226	NJLL-TX1				32	O	48	3.90
270	NJLL-TX1				27	O	2	3.54

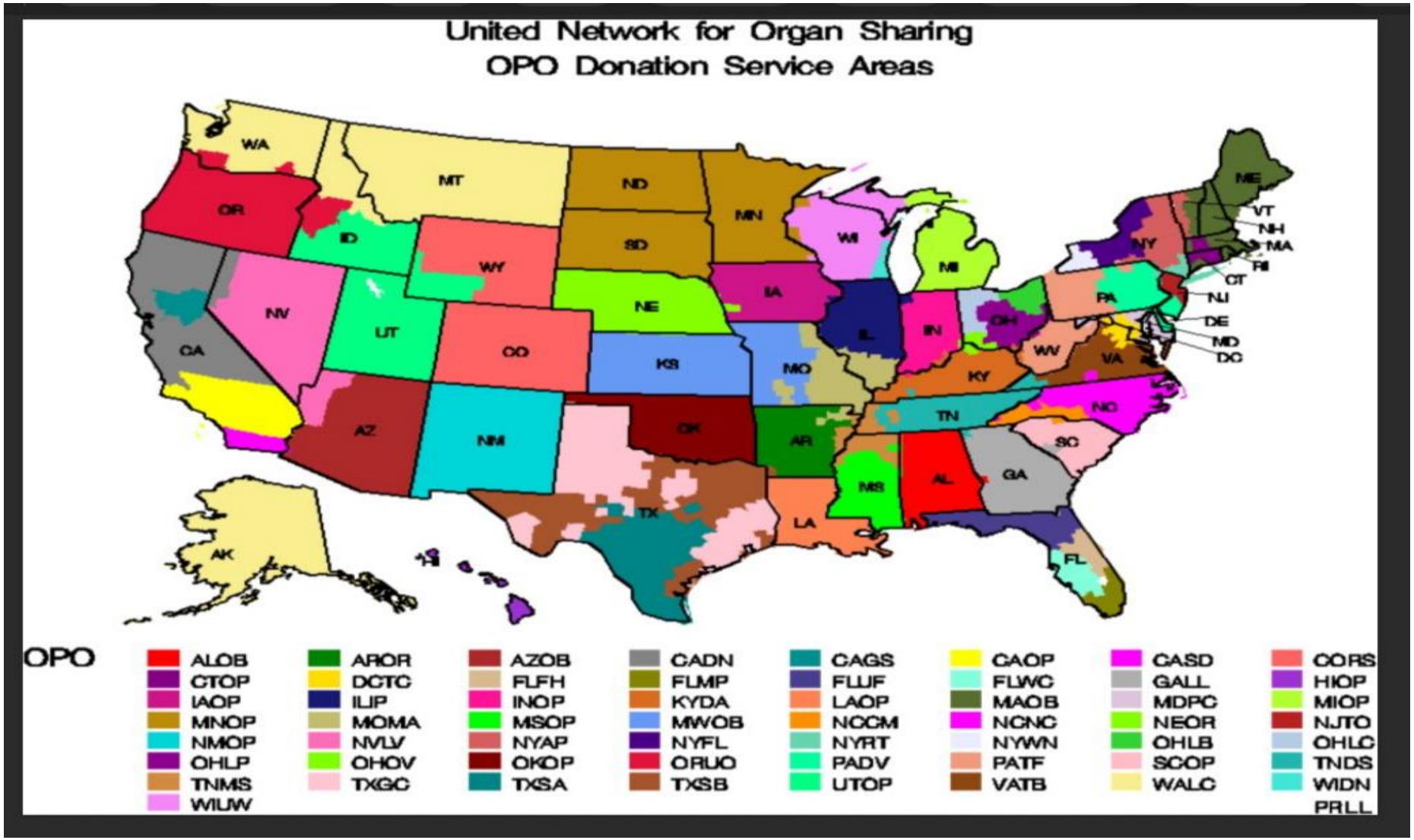
Sample of match run in UNET

Recent Allocation Changes

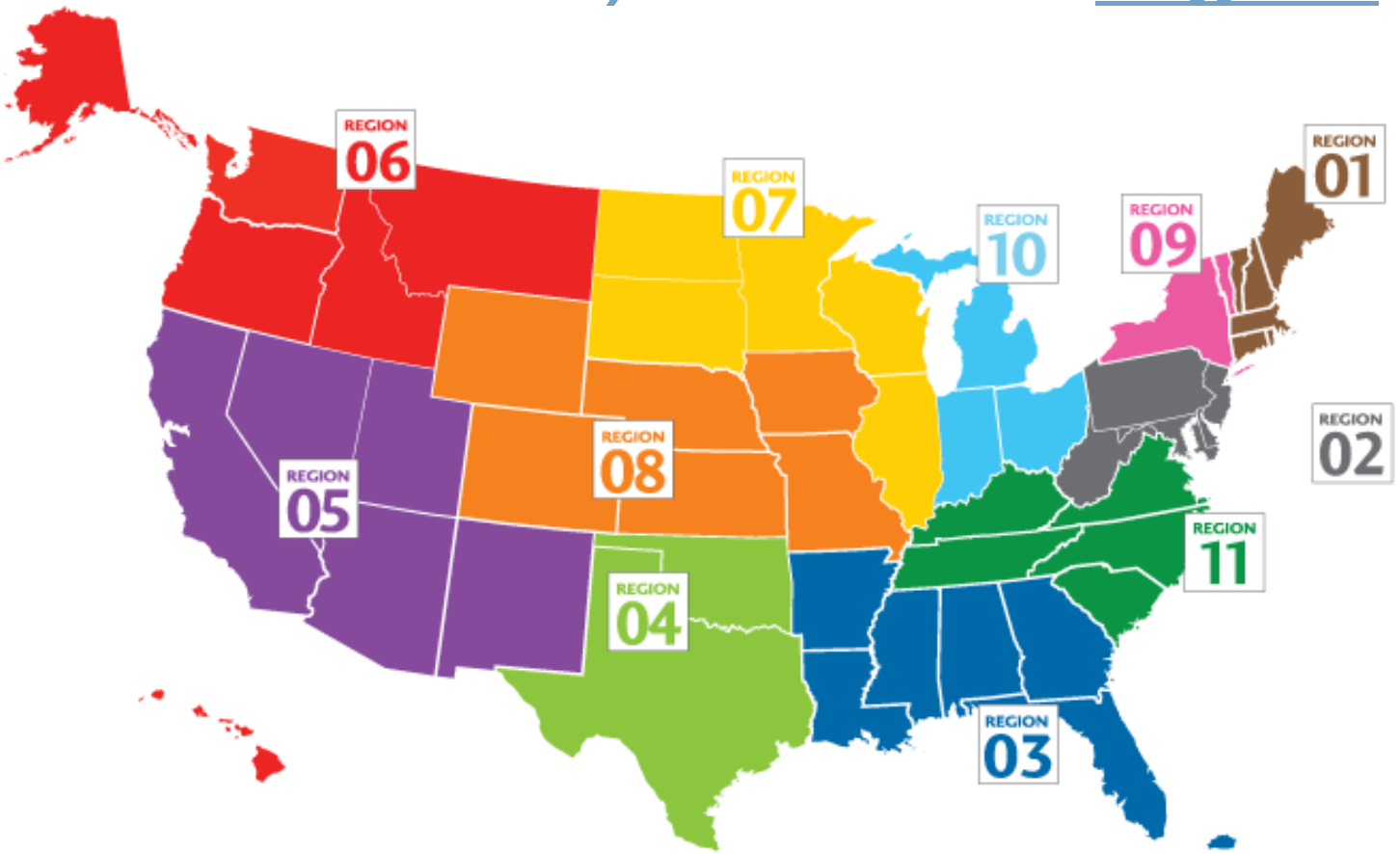
Previous Allocation System (prior to March 2021)

- A three-tiered approach was used (local/DSA, regional, and national).
- Most kidney/pancreas offers would go first to candidates within the same donation service area (DSA) where the donor hospital is located.
- Organ offers not accepted at the DSA level were made to candidates within the same OPTN region (regional)as the donor hospital.
- Offers not accepted at the DSA or regional level were then made to candidates listed at transplant programs anywhere(national) in the United States.

Previous Allocation System (prior to March 2021)- based on **local, DSA**

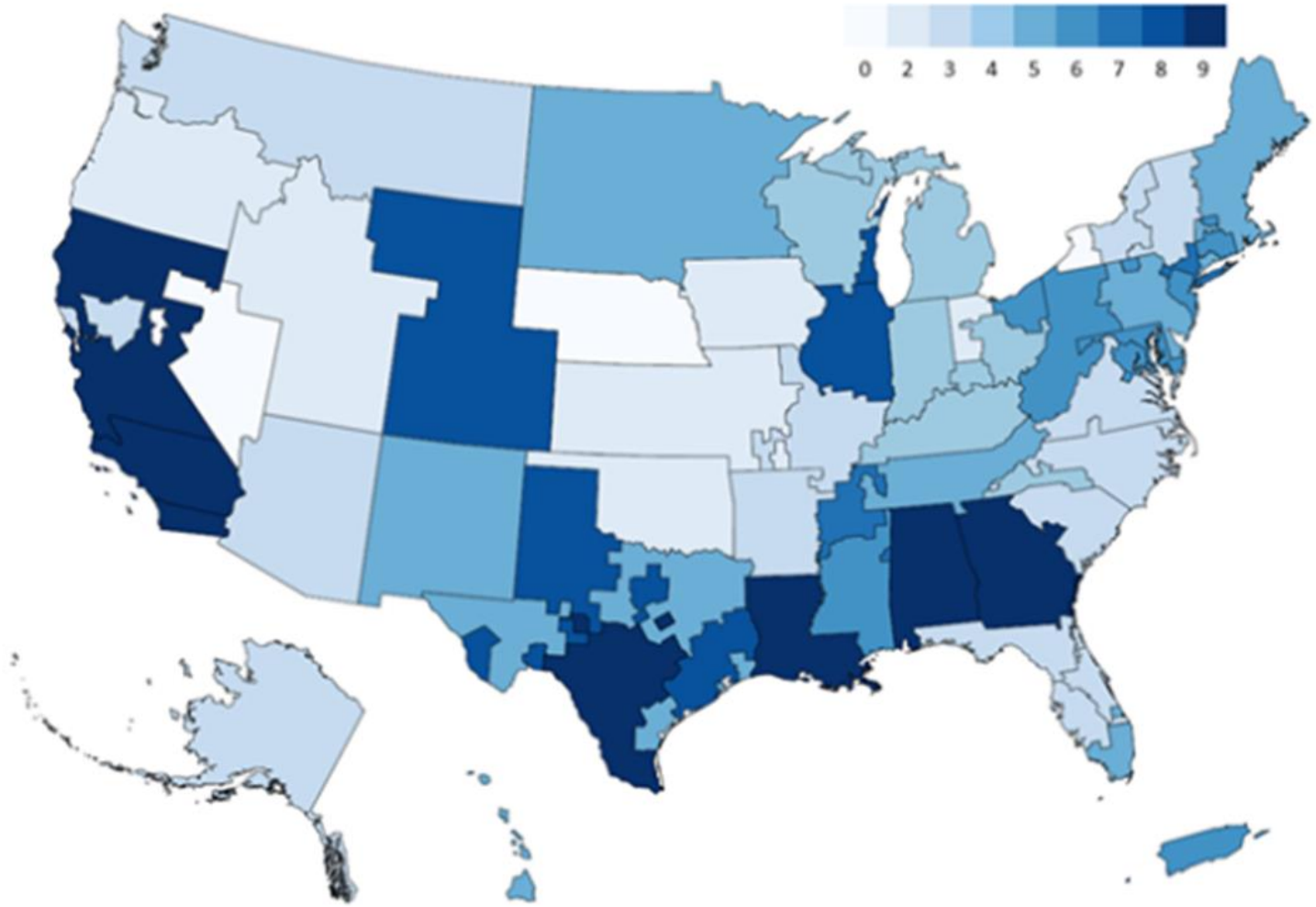


Previous Allocation System (prior to March 2021)- based on **region**



Virtua Health

Estimated Median Waiting Times



OPTN 2017

Virtua Health

Reason for change:

- The Final Rule (hereafter “Final Rule”) sets requirements for allocation polices developed by the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS), “including the use of sound medical judgement, achieving the best use of organs, preserving the ability for centers to decide whether to accept an organ offer, avoiding wasting organs, avoiding futile transplants, promoting patient access to transplantation and promoting efficiency.”

- The Final Rule also includes a requirement that policies “shall not be based on the candidate’s place of residence or place of registration, except to the extent required”

OPTN 2018

Virtua Health

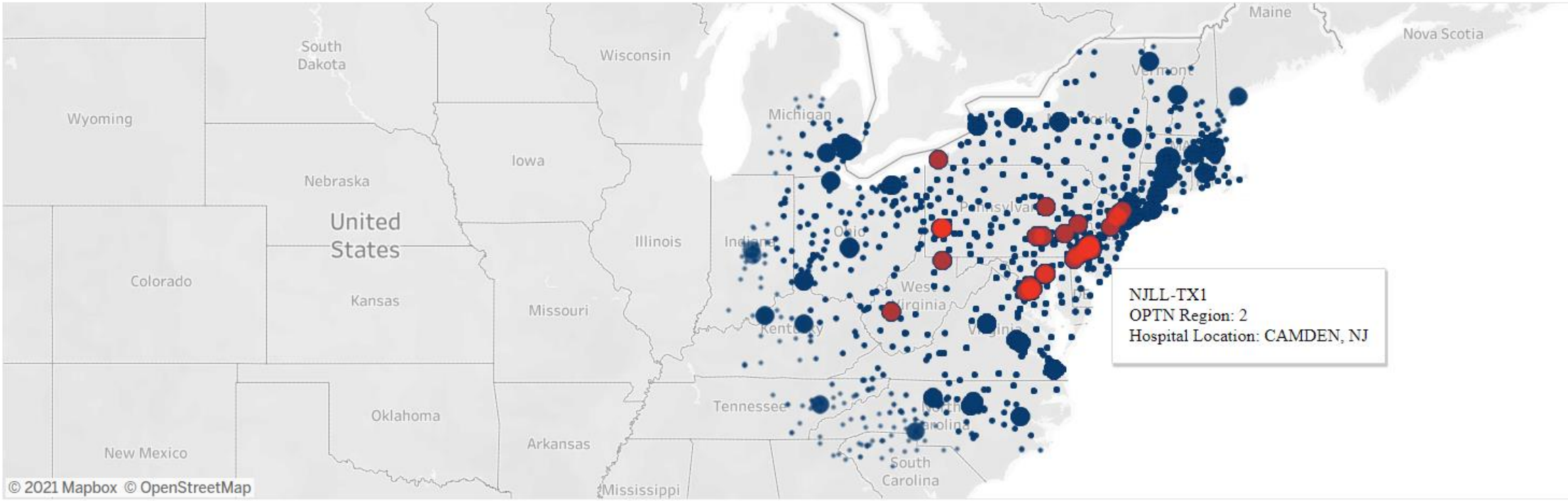
New Allocation Changes 2021

- Distribution will no longer be based on DSA or Regional Allocation

- Kidney and pancreas offers will be offered first to candidates listed at transplant hospitals within 250 nautical miles of the donor hospital. Offers not accepted for any of these candidates will then be made for candidates beyond the 250 nautical mile distance.

- National priority in allocation

View of 250 NM Radius at NJLL



OPTN 2021

Virtua Health

Allocation

- Primarily within 250 NM

- National
  - Rationale for why patients would get allocation nationally:
    - cPRA 100
    - 0Ag MM
    - EPTS of recipient <20%, Donor KDPI <20%
    - Registration of recipient prior to 18 years of age
    - A2 donor to B recipient
    - Also- enbloc, dual acceptance listed

Dual Listing

- Prior to changes in 2021 candidates listed at two different hospitals just a short distance apart from each other, and a short distance from a donor hospital, could appear much higher or lower on a match just because their hospitals are in different DSAs or regions

- New allocation is based on distance and medical need.

Outcomes of recent changes:

- The post-policy era saw a **22 percent increase** in kidney transplants when compared to the pre-policy era, from 4,926 to 6,025
- The average number of transplants per week **increased by more than 19 percent** in the post-policy era, from 331 to 395
- Transplants **increased for all age groups, blood types, CPRA and diagnoses**

UNOS October 21, 2021

Virtua Health

Outcomes of recent changes:

Transplants

Figure 33 and **Table 32** show deceased donor kidney transplants from December 01, 2020 to June 30, 2021 by policy era. There were 4926 transplants performed pre-policy, and 6025 performed post-policy.

Figure 33: Deceased Donor Kidney Transplants December 01, 2020 - June 30, 2021 by Policy Era

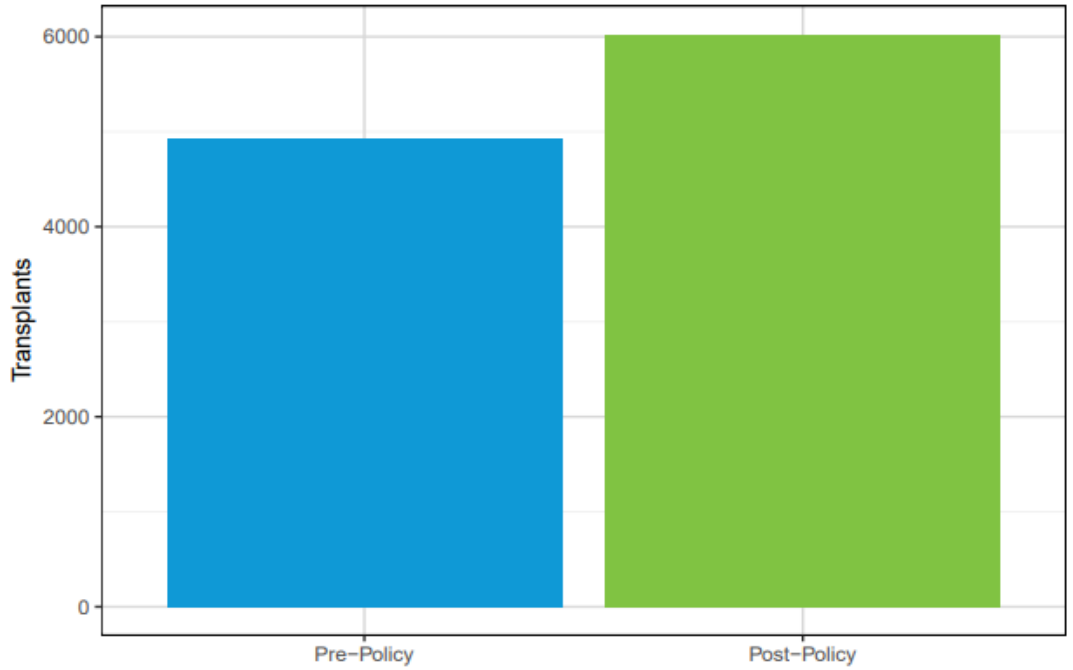


Table 32: Deceased Donor Kidney Transplants December 01, 2020 - June 30, 2021 by Policy Era

Era	Transplants
Pre-Policy	4926
Post-Policy	6025

UNOS October 21, 2021

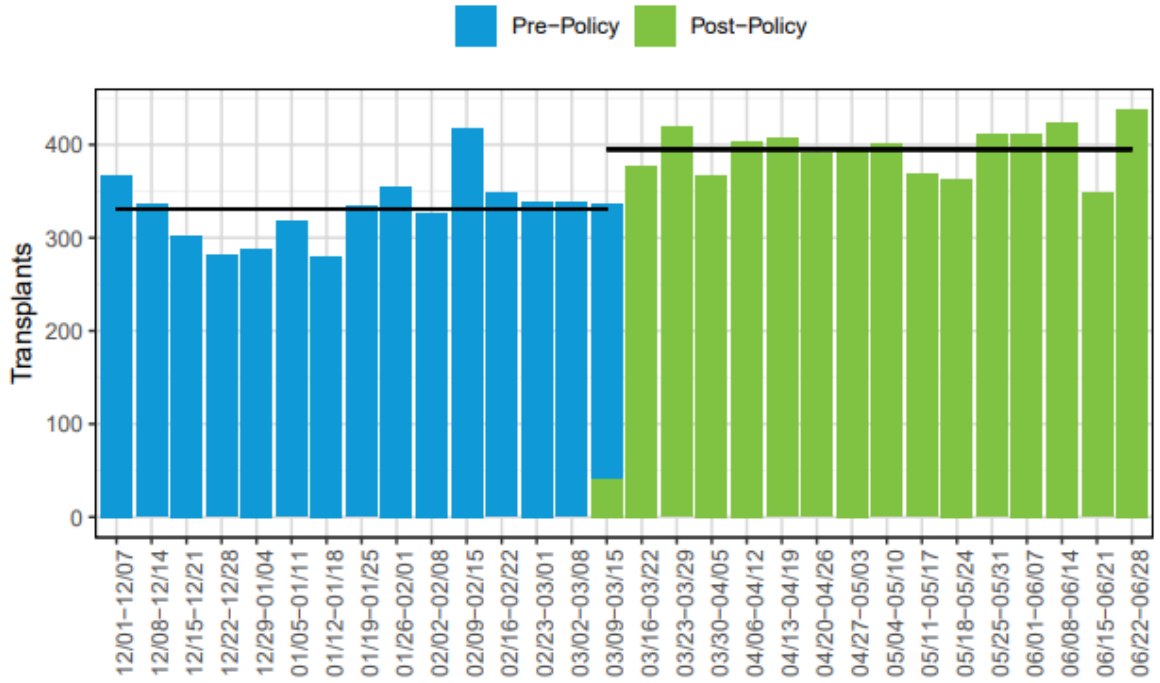
Virtua Health

Outcomes of recent changes:

OPTN Kidney Transplantation October 8, 2021

Figure 34 shows weekly deceased donor kidney transplants from December 01, 2020 to June 28, 2021. The average number of transplants per week was 331 pre-policy and 395 post-policy. A table showing transplants by week is provided in the **Appendix**.

Figure 34: Weekly Deceased Donor Kidney Transplants December 01, 2020-June 28, 2021 by Policy Era



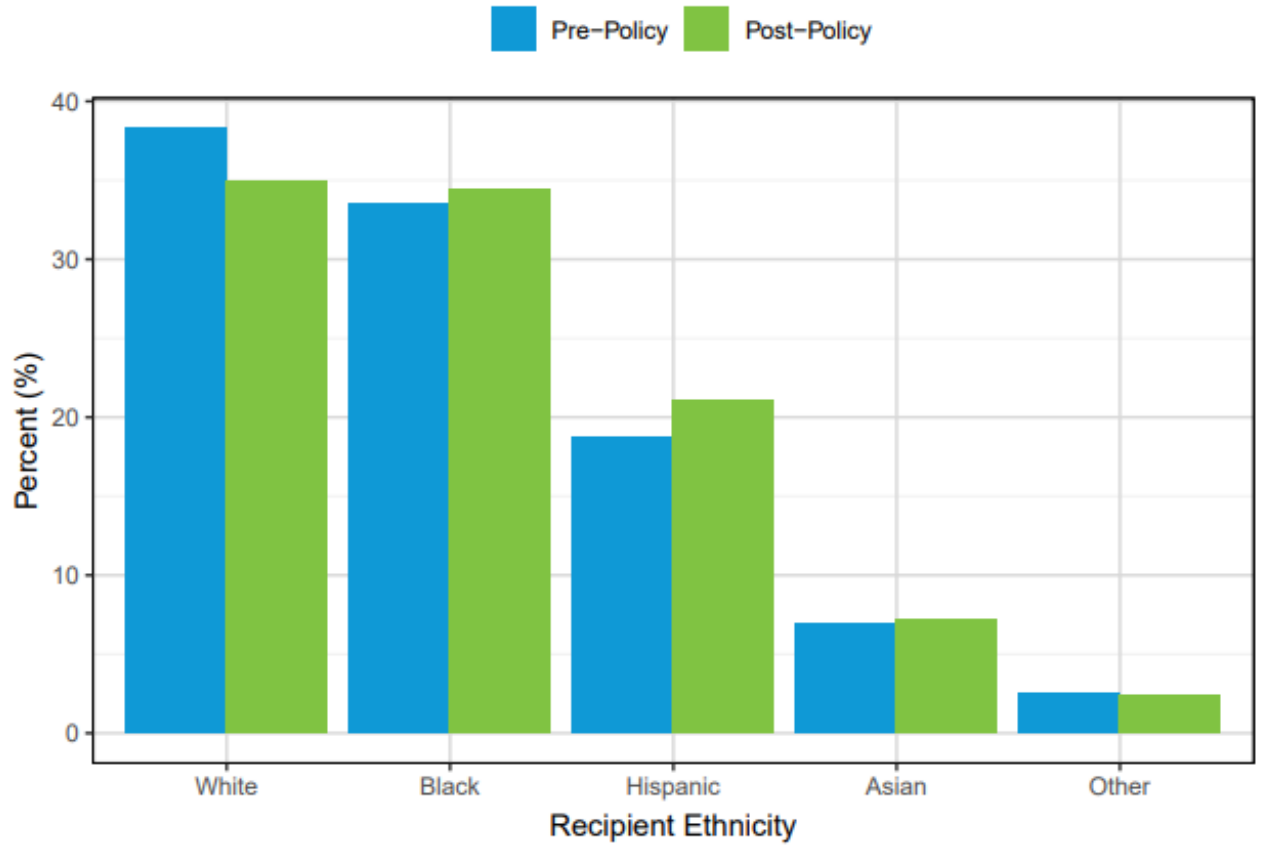
Lines represent the average number of transplants per week.
Some weeks shown in the figure include federal holidays.

UNOS October 21, 2021

Virtua Health

Outcomes of recent changes:

Figure 36: Deceased Donor Kidney Transplants from December 01, 2020 - June 30, 2021 by Policy Era and Recipient Ethnicity



UNOS October 21, 2021

Table 34: Deceased Donor Kidney Transplants from December 01, 2020 - June 30, 2021 by Policy Era and Recipient Ethnicity

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Outcomes of recent changes from a Center Perspective

- More organ offers, more deceased donor transplants
- More DCD donor organs being offered
- Unpredictable waiting time or monitoring of a “priority list”
- Logistical challenge of dealing with outside OPOs, increase distance to transplant center
- More delayed graft function due to DCD donors and increased cold ischemia times
- Working with unpredictable timing challenges. As sharing of organs is more broader, dealing with multiple outside transplant centers and positioning in match run quickly changes

Key Points, New Allocation

- **Goal to accomplish a continuous distribution system**
- Implemented to be more align with the Final Rule that policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by other requirements of the Rule
- Removal of DSA (Donor Service Area) and OPTN Regions as geographical constraints in allocation
- **There is now more broader sharing**
- Allocation is now based on a 250 nautical mile radius fixed distance from the donor hospital
- Candidates are allowed up to 2 proximity points with allocation depending on distance from donor hospital to transplant center- within the 250 mile radius. If the organ is not accepted within the 250 mile radius allocation, outside of the circle can have up to 4 proximity points awarded
- 250 NM radius has also been added to pancreas allocation

Key Points, New Allocation

- Added medical urgency, in cases where dialysis access has been exhausted as priority factor
- Factors such as dialysis waiting time, cPRA, degree of match, previous living donor, pediatrics, and longevity matching are still applied
- Transplant centers will now be working with multiple OPOs
- New allocation criteria aims to avoid organ wastage
- May see more marginal kidneys utilized, DCD donors, delayed graft function and need for dialysis after transplant

Resources

- Resources by Organ Type - Kidney & Pancreas - OPTN (hrsa.gov)
- New policy adopted to improve kidney, pancreas distribution - OPTN (hrsa.gov)
- OPTN/UNOS Kidney and Pancreas Committees Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution, Concept Paper, Scott Castro M.P.P. and Abigail Fox M.P.A. UNOS Policy & Community Relations Department, 2018
- OPTN Policies Effective as of Oct 7 2021 [Liver] (hrsa.gov)
- Kidney (hrsa.gov)
- Kidney transplants increase across all populations following policy changes - UNOS

Questions?

Thank you for Attending Today!!