Kidney Transplant Recipient Selection
Reconciling Patient versus Program Priorities

- Goals of transplant for the individual patient
- Indications for transplant
- Risks versus benefits - patient versus program priorities
- Government oversight primer
- Program vs. patient issues - case examples
Goals of Kidney Transplantation

- Quality of life
- Life Extension
- Reduce Costs
Years of Remaining Life Expectancy
With & Without Kidney Transplant

NEJM Dec 2, 1999

Cost of ESRD

Total ESRD Expenditures per person, per year, by Modality

ESRD Medicare Spending:
1.3% of Medicare population
8% of Medicare expenditures
$28 Billion

USRDS 2010
Indications for Kidney Transplant

- ESRD
- Chronic Maintenance Dialysis
  - or
- GFR <20 ml/min

Graft Survival in 2405 Paired Kidney Transplants: Short vs. Long Time on Dialysis

Transplantation 2002; 74: 1377
Kidney Transplant Exclusion Criteria

- Why have exclusion criteria?
  - Benefits must outweigh risks
  - Risks associated with transplant
    - Cancer
    - Infection
    - Cardiovascular risk
    - short term vs. long term
Transplant Government Oversight

- **SRTR** - Scientific Registry of Transplant Recipients
  - Charged with reporting program specific performance information, at least every 6 months.

- **MPSC** - Membership & Professional Standards Committee of the OPTN
  - Reviews a transplant program to determine if it has a low graft or patient survival compared to expected rate.
Program Quality Indicators

- Donor and Recipient risks are adjusted to determine expected outcomes
- No risk adjustment for CV disease, smoking, lack of social support, functional status, income, frailty, etc.
- BMI adjusted only for >30 (no adjustment for the very obese)
- Age adjusted only for >65 (no adjustment for the very old)

Program Deficiency

- A program is “flagged” as a “condition level deficiency”
  - if there is a 75% probability that graft failure rate or patient mortality is 20% higher than expected
  - OR
  - if there is a 10% probability that graft failure rate or patient mortality rate is >2.5x greater than expected
Chance of Flagging (Condition Level Deficiency)

- Large programs - 6%
- Medium programs - 16%
- Small programs - 7%
- “False Flagging” rate = 5%

210 days to fulfill a System Improvement Agreement
- extremely costly
- requires expensive outside consultants
- based on data which is > 3 years old
- can expand to CMS review of entire hospital
**Condition Level Deficiency**

- Most programs are “flagged” for patients “without” risk adjustors
- Suggests there is significant unaccounted risk in patients with CV disease, the very old, perhaps the very obese, those with low income & lack of social support
- The number of transplants drop significantly after a program has been flagged
- The outcomes at flagged programs are still far better than those of wait listed patients

**Transplant Wait List versus Number of Transplants**

[Graph showing the number of registered kidney candidates vs. kidney transplant operations from 2000 to 2012. The graph indicates a significant increase in transplant operations compared to the number of registered candidates. Source: U.S. Department of Health & Human Services]
Patient vs. Program Priorities

Patient risk vs. benefit

Program risk vs. benefit

Kidney Transplant Risk vs. Benefit

QOL & relative life expectancy compared to dialysis

Life expectancy compared to SRTR “expected”

Patient

Transplant Physician

Transplant Program
Case #1

- 51 yo female with ESRD - membranous nephropathy
- Home nocturnal peritoneal dialysis, works as a teacher, widow, lives independently, shops, cleans, knee arthritis - able to walk up a flight of stairs (slowly)
- BMI = 46, OSA - uses CPAP
- 6 min. walk test: 450 meters, but very fatigued, O2 sats >94%
- Echo EF = 60%, 2/4 DD, no pulm HTN, neg DSE
- No living donor. Should she be listed for a deceased donor?
Kidney Transplant in Obese Patients

- Obese patients have a lower risk of death compared to non-obese patients on dialysis ("Obesity Paradox")
- Obese patients might have an increased risk of death after transplant compared to non-obese patients
- What is the relative risk of death in obese patients with transplant compared to dialysis?

Effects of Obesity on Kidney Transplantation Outcomes: Systemic Review and Meta-Analysis

- 21 studies, 9296 patients
- Mean BMI 30-34, very few >40
- Obesity was associated with DGF and wound complications
- Graft loss and death were associated with obesity only in those receiving a kidney transplant before the year 2000
- No association of obesity with graft loss and death in those receiving a kidney transplant after the year 2000

Transplantation 2014; 98: 167-176
Risk of Death in Transplant Recipients Compared to Wait-listed Patients by BMI - 1 year post transplant

USRDS Data 1995-2007
208,498 patients

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<th>BMI</th>
<th>SCD recipients</th>
<th>ECD recipients</th>
<th>LD recipient</th>
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<td>0.52 (0.37, 0.72)</td>
<td>0.54 (0.33, 0.78)</td>
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46-48% reduction in risk, but more risk than non-obese

Am J Transplantation 2013; 13: 2083

Decreased Functional Status is Associated with Death in Transplant Recipients

UNOS data, >10,000 patients, SF-36 measurement data

Case #1

Patient perspective:
- Her life expectancy would be greater with transplant compared to dialysis, even with BMI >40
- She would have a better quality of life with transplant
- She is at greater risk of DGF and wound complications

Program perspective:
- She might have a higher risk of death compared to non-obese patients
- SRTR data is not adjusted for extreme obesity, putting the program at risk for review by the MPSC
- Mitigating issue: her functional status is reasonable

Case #2

- 66 yo male with ESRD due to DM2, HD x 1 year, dialyzes with a fistula
- CAD - stents in LAD & RCA
- Iliac artery stents
- Echo - EF = 50%, 2/4 DD, RVSP = 50
- DSE - equivocal area of ischemia, anterior distribution. Cardiologist states “low risk for surgery”.
- BMI = 28, smoking 50 pack-yrs, ½ PPD now, moderate COPD on PFT’s
- He walks around his house, but uses wheelchair to get from parking lot to dialysis. He does not walk up stairs. He thinks he could walk about a block.
- No living donor. Should he be listed for a deceased donor?
Cardiovascular Disease in Kidney Transplant

- Lower rates of CV disease in transplant population compared to dialysis population
- Higher rates of CV disease in transplant population compared to general population
- 30% of graft loss is due to CV death
- Greatest risk is early in the transplant course
- Dominated by diabetes and the elderly
- Pre-transplant CV disease predicts post-transplant CV disease and CV disease is 10-20x higher in the dialysis population compared to general population
- CV disease in ESRD is different - more CHF, more medial calcification, more arrhythmia, etc.
- Pulmonary HTN is present in 20-70% of dialysis patients, often persists post-transplant and is associated with high mortality in both populations

Time to Equal Survival

Survival is lower in the transplant group for a period of time (time to equal survival), but thereafter greater than in the waitlist group.
Days to Equal Survival: Kidney Transplant Recipients Compared to Wait-Listed Patients, >64 Years Old

Registry Data - 25,000 transplant recipients

Risk Factors: CAD, CHF, CVA, PVD

Death Rate = 23/100 pt-yrs

Coronary Artery Disease in a Large Transplant Population


Am J Transplantation 2011; 11:2665
Case #2

Patient perspective:
- He hates dialysis and is looking for a better quality of life
- He wants to take his chances on extending his life with transplant

Program perspective:
- High risk of early death given CAD, PVD and pulmonary HTN
- SRTR data is not adjusted for CV disease
- Additional issue: poor functional status

How comfortable are you with risk?
What Should Criteria be for Listing?

- Patient anticipated to have at least a 5 year life expectancy?
- Patient anticipated to live longer than expected wait time?
- What level of relative benefit of transplant over dialysis is desired?
  - Life expectancy benefit?
  - Quality of life benefit? - How to quantitate?
- How important are the transplant center’s concerns relative to the patient’s?

Growth of Kidney Transplant Wait List

![Graph showing the growth of kidney transplant wait list from 1999 to 2011. The graph shows two lines: one for active patients and one for inactive patients. The number of patients in thousands is plotted on the y-axis, and the year is plotted on the x-axis.](image)
Societal Concerns

- How should organs be distributed given that they are such a scarce commodity?
- When making individual patient decisions what is our responsibility to others on the wait list?
- Collectivism vs. Individualism