

Déjà vu: Re-Evaluating Patients on the Waiting List: What, When, Why, & How?

NATCO Symposium for Advanced Transplant Professionals

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Objectives

- Demonstrate understanding of the necessity of waitlist management by listing 3 regulatory requirements related to waitlist management
- Describe the essential organ specific components of waiting list re-evaluation & management
- Identify proven techniques to utilize in the development and implementation of an effective waiting list process

Why

Quantity

- Increase the numbers of patients transplanted
- Increase the numbers of organs transplanted
- Every active candidate ready at all times to accept an organ offer
- Decrease in organ wastage

Quality

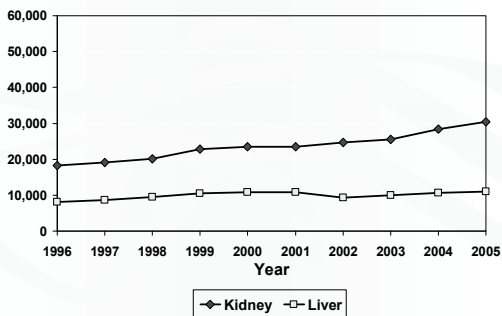
- Improve quality of organs transplanted by decreasing ischemic time
- Every candidate in optimal condition to undergo organ transplant
- Matching appropriate candidate to each organ offer

Overview of Waiting List

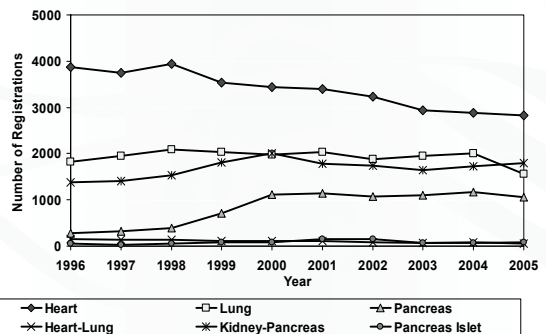
- Total 104,771
- Kidney 78,381
- Liver 17,143
- Pancreas 1,649
- KP 2,342
- Heart 2,694
- Lung 2,237
- HL 103
- Intestine 222

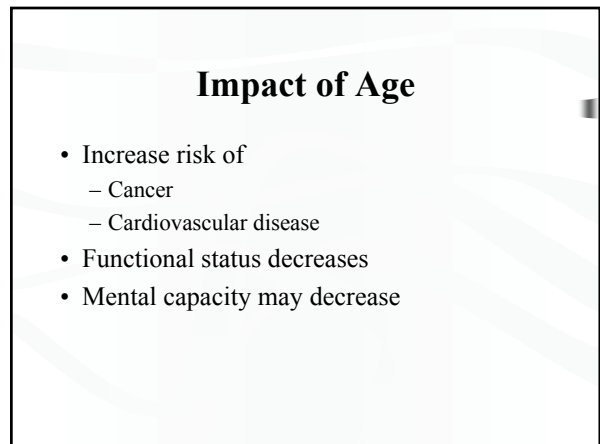
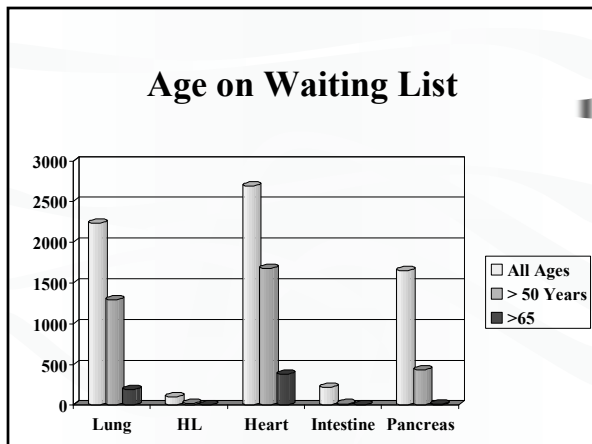
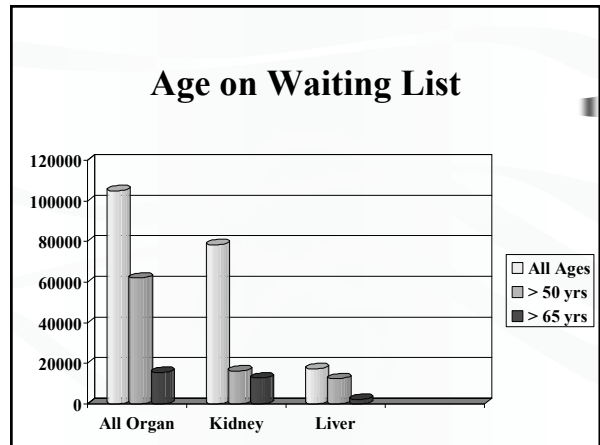
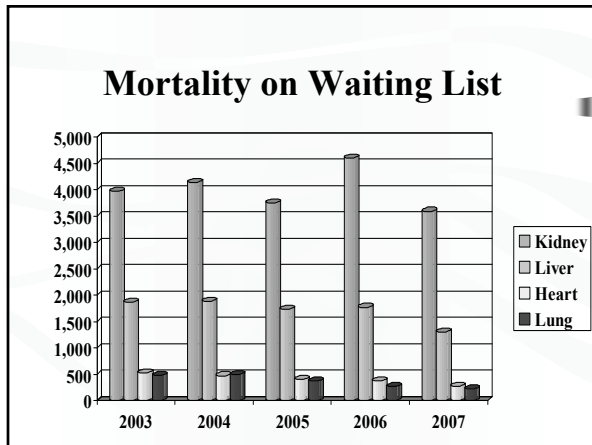
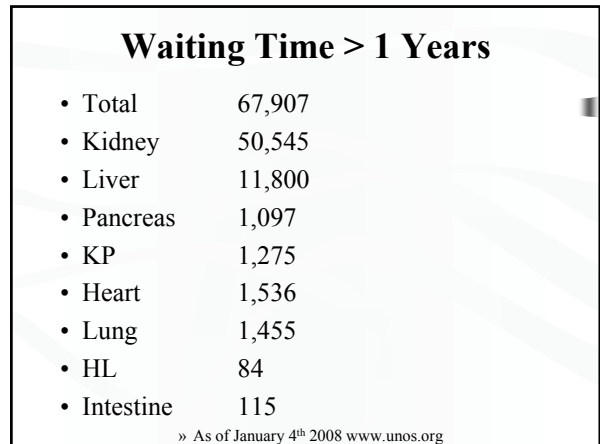
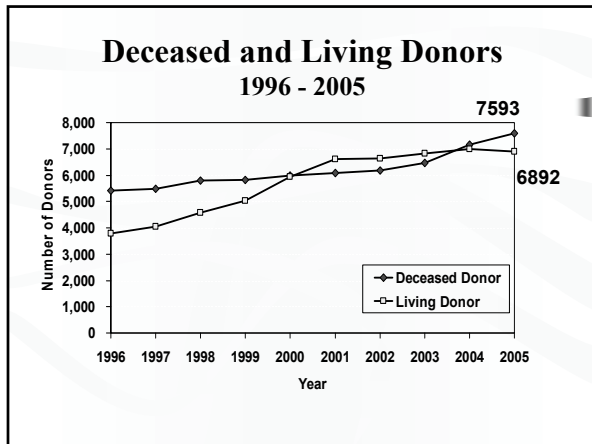
» As of January 4th 2008 www.unos.org

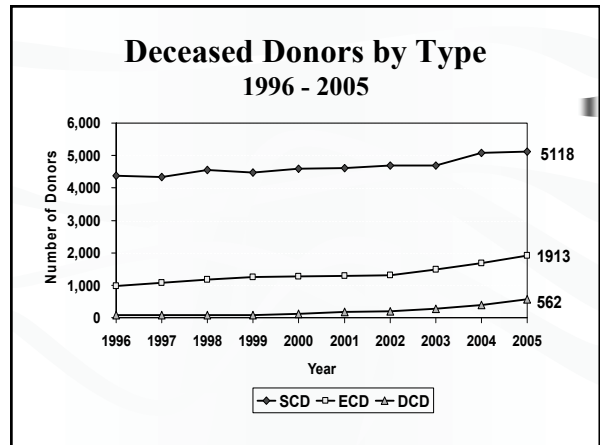
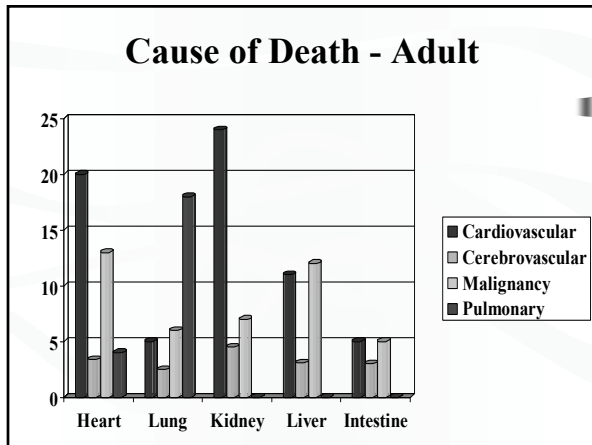
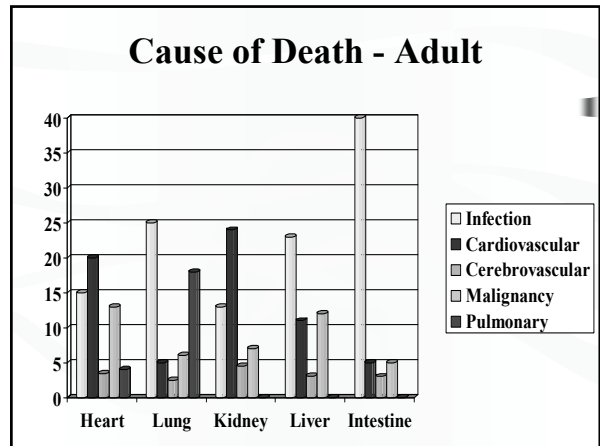
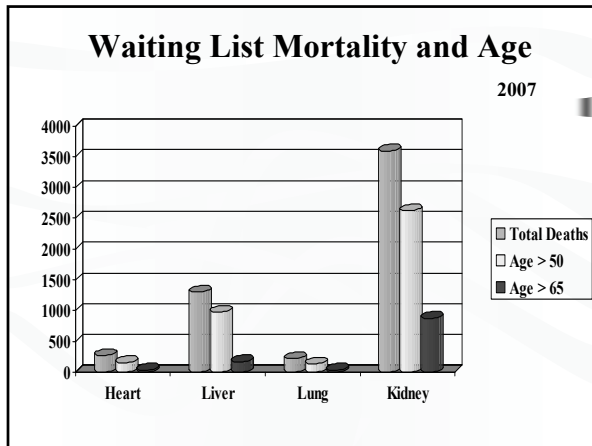
Waiting List Additions 1996-2005



Waiting List Additions 1996-2005







Donor Recipient Matching

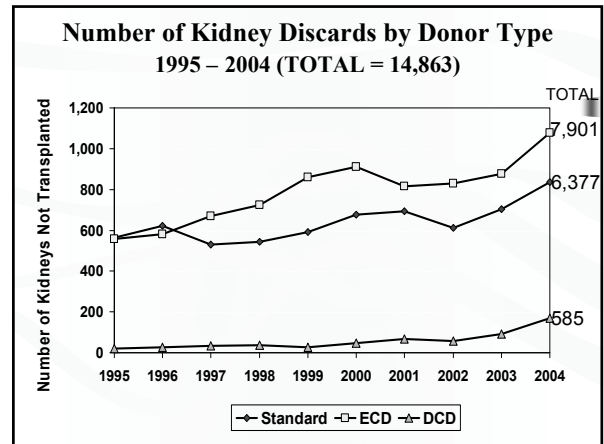
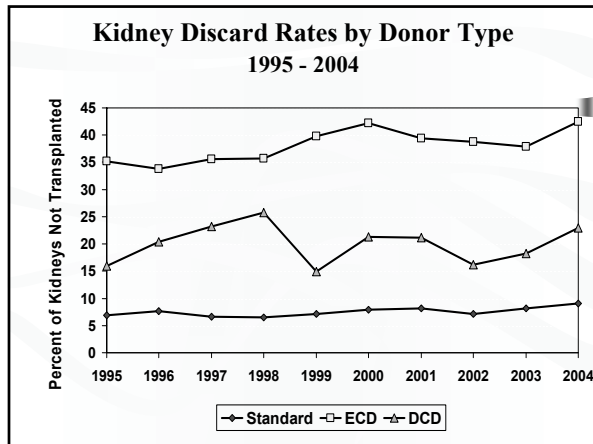
ECD

- Definition too broad in kidney
- No definition for liver, heart or lung
- Not all candidates are suitable
 - marginal organ + sick recipient = poor outcome
- Not all suitable candidates will consent

Donor Recipient Matching

DCD

- Not suitable for all candidates
- Not all candidates will consent
- Suggested better outcomes with DCD kidneys than ECD kidneys
- Long term outcomes in DCD liver unknown
- Reproducing short ischemic times over larger sharing areas may be problematic in DCD liver and lung



Regulatory Oversight of Wait List

- CMS Condition of Participation
- Joint Commission Standards
- UNOS/OPTN Policies and Bylaws

CMS Patient & Living Donor Management 482.94 Standard: Waiting List Management

- Transplant centers must keep their waiting list up to date on an ongoing basis including
 - Update clinical information
 - Removal on death or transplant or any other reason patient should no longer be on the list
- Notification of OPTN no later than 24 hours after removal from the centers waiting list

CMS Patient & Living Donor Management 482.94 Standard: Patient Records cont

- On removal from waiting list for any reason other than
 - Death
 - Transplant
- Document in patients record that the patient (& dialysis unit) was notification within 10 days of the removal

JCAHO Waitlist Management PM.8.0

- Transplant program waiting lists are up to date
 - Patient specific clinical information updated on ongoing basis in the medical record
 - Ineligible candidates removed from the waiting list
 - Removal within 24 hours of transplant or death
 - OPTN immediately notified of any patients removal from waitlist

JCAHO Medical Record PC.5

- Transplant center initiates and maintains a medical record for each patient eligible and waiting for transplant
 - Candidate notified at least annually of placement, even if no change in status
 - Notified within 10 days of removal for reason other than transplant or death
 - Designated dialysis unit is notified of any changes

OPTN Bylaws Appendix B, Section II,F

- Transplant hospitals expected to notify candidates in writing within 10 business days and maintain documentation
 - That they have been placed on the waiting list
 - Include date of listing
 - Have not been placed on the waiting list
 - That they have been removed from the waiting list when removed for reasons other than death or transplant
 - Notification to include Patient Services Hotline

UNOS/OPTN

OPTN Policy 3.6.1 Liver

- List candidates with realistic donor weight range

OPTN Policy 3.3.3 Kidney

- Clearly define and enter renal acceptance criteria in Unet

OPTN Policy 3.5.3.3 Kidney

- List with accurate expanded donor acceptance information

UNOS/OPTN

OPTN Policy – Removal from Waiting List

- Must be removed within 24 hours of death or transplant with either deceased or living donor
- 3.2.4.1 Kidney
- 3.8.6 Pancreas
- 3.6.6 Liver
- 3.7.14 Thoracic
- 3.11.5 Intestine

OPTN Policy 3.2.3

- Waiting time transferal and multiple listing
- Inform patients of
 - Waiting Time Transferal
 - Multiple Listing option
- Maintain documentation in medical record

Electronic Organ Offer - Donornet

- Multiple simultaneous organ offers
 - Decreases time to provide donor information
 - Decreases time to identify final candidate
- Significant increase in total number of organ offers to multiple candidates
- Refusal codes inputted upon refusal

How?

- Who will do re-evaluations
- Impact of existing resources
- Additional resource assessment
- Where to begin?

Resource Assessment

- Clinic Volume
 - # of candidates on waiting list
 - Frequency of visits based on protocol
- Space
 - # of additional f/u visits/week or month
- FTE's
 - MD or NP role
 - Clinical Transplant Coordinator
 - Social Work
 - Financial Counselor
 - Scheduling staff

Establish Protocol

- Support of
 - Medical/Surgical Director
 - Administrator
 - Coordinators
 - Social Workers
 - Financial Counselors
- Research published literature
- Understand the organ specific listing criteria
- Understand the UNOS/OPTN & CMS regulations

What & When?

- What to re-evaluate
- What tests are appropriate
- Recommended frequency of tests
- What to do with results

Kidney

2002 Recommendations

Matas et al

- H & P annually
- Infection – Hepatitis & HIV annually
- Cancer – American Cancer Society Guidelines
- Cardiac
 - Non diabetic, asymptomatic – nil
 - Asymptomatic & ≥ 2 risk factors
- Stress Q 1-2 Years

National Conference on the Kidney Wait List

AST, ASTS, SRTR, AOPO, UNOS, NIH, ASHI, DoT, NKF

Management of the List

- Facilitate rapid placement of deceased donor kidneys to a prepared population of potential recipients
- Minimize repetition of onerous + expensive testing

Consequence

- Cancelled Transplant
- Transplant under unnecessary or unrecognized risk

Recommendations

- Unet based communication between Tx center, dialysis units & HLA labs
- Assign ‘wait-list-manager/coordinator’ to facilitate annual communication with Pt.
- Preventative Health Measure – Disease Outcome Quality Initiative (DOQI)
- HLA on evaluation and Q month x 2, then every 3 months.
- Change UNOS/OPTN policy regarding wait time accrual as status 7

AST Clinical Practice Guidelines

- 192 (67%) of program responded to survey
- Routine contact (visit or phone) is required
- High risk & KP candidates high profile
- Annual screening for CAD in asymptomatic candidates based on documented CAD, DM, advanced age, or obesity.
- Non invasive cardiac screening used
- Dialysis nephrologists or patient is expected to inform the Tx Center of intercurrent events
- Prevalence and progression of CAD

AST Recommendations

- Develop consistent organized system
- Develop open communication with nephrologists & dialysis units
- Describe clear expectations to patient, dialysis units and nephrologists
- Pts at high risk for CAD need repeat studies to r/o covert progression

AST Recommendations

- High risk” needs to be studied and validated in prospective trials
- Assess usefulness of non invasive cardiac imaging
- Standardized criteria for placing patients on hold or removing from waiting list.
- Meticulous attention to overall health of candidates

Kidney Transplant Center Survey

- Survey sent to Medical & Surgical Director of Kidney Transplant Program in the US.
- 64/257 (25%) centers responded.
- 41 programs have formal protocol in place for 10 3 years
- 44% of programs have no formal protocol in place

Results of Survey

- 80% of programs reported the Transplant Center completes the re-evaluation.
- 20% reported the dialysis nephrologists or the cardiologist to be responsible
- Wide variation in practices related to
 - Cardiac re-evaluation
 - Infectious disease monitoring
- Recommendation on PRA not followed
- 75% of respondents would like standardized criteria established

Recommendations for Kidney

- Repeat visit every 6 months, every year or every other year based on diagnosis, age and risk factors
 - Telephone screening to identify candidates at risk medically or psychosocially
 - Identify top 10 waiting time by ABO
 - Match run – actual or dummy
- PRA monthly or monthly x 3 months, then every 3 months

Recommendations

- Serology
 - EBV, CMV, HSV Toxo – annual screening not indicated
 - CMV neg – annual if prophylaxis determined by recipient status
- Infectious Disease
 - HIV - annual for high risk pts
 - HCV + HBV - annual for Elisa negative pts
 - HCV + - ongoing evaluation
 - HBV - immunization, antibodies annual + booster
 - PPD + - annual Chest X-ray
 - Strongyloides - annual in endemic areas

Recommendations

- Cardiac
 - Non diabetic, asymptomatic, normal evaluation – nil
 - Asymptomatic & ≥ 2 risk factors – stress test 1-2 years
 - Dialysis > 3 yrs (kidney candidate)
 - Male > 45 yrs
 - IHD in 1st degree relative
 - Current smoker
 - Hypertension
 - Cholesterol > 250 mg/dl
 - HDL < 35 mg/dl
 - Stent or prior intervention

Heart

Recommendations

- Repeat visit every 3 months
- PRA
 - >10% 1-2 months
 - VAD 1-2 months
 - 2 weeks after transfusion then 9 month x 6 months
- Assessment of Heart Failure
 - Cardiopulmonary exercise test with RER annually
 - Echo annually
 - Right Heart cath – every 6 months
 - ECG annually

Recommendations

- Labs –
 - Routine disease monitoring Q 3 months
 - ABG eval only
- Pulmonary
 - PFT's eval only
 - CXR annually
- Infectious
 - Dental annually
- Infectious Disease
 - Serology on eval only

Lung

Organ Specific Criteria - Lung

Forced vital capacity (FVC)
O2 required at rest
Body mass index (BMI)
Functional status
Six-minute walk distance
Serum Creatinine

Primary Pulmonary Hypertension

- ISHLT recommends every 6 months
 - Six minute walk distance
 - History of hemoptysis requiring hospitalization
 - Pro-BNP [brain natriuretic peptide] level
 - Assessment of right sided heart failure
- ISHLT recommends every 12months
 - Heart catheterization
 - Echocardiogram
 - New York Heart Association functional status

Liver

Organ Specific Criteria - Liver

- MELD/PELD allocation system
- Frequency of labs defined by MELD/PELD score
- HCC screening for prioritized patients determined by policy
- Not defined by policy
 - Screening post tumor treatment
 - Frequency of chest CT or Bone scan
 - AFP usually every 3 months unless increasing

Recommendations

- Repeat visit
 - annually
 - based on MELDPELD score
 - etiology of liver disease
- Other
 - Bone densitometry annually in high risk

Recommendations

- HCC Diagnosis
 - CT/MRI Q 3 months for continued prioritization
 - CT/MRI one month post tumor treatment
 - CT chest + bone scan for high risk tumor cases
 - AFP Q 3 months
- HCC Screening
 - CT/MRI or Sonogram Q 6-12 months in cirrhotic + hepatitis B
 - AFP Q 3 months

Recommendations

- Serology
 - EBV, CMV, HSV Toxo – annual screening not indicated
 - CMV neg – annual if prophylaxis determined by recipient status
- Infectious Disease
 - HIV - annual for high risk pts
 - HCV + HBV - annual for Elisa negative pts
 - HCV + HBV + HIV disease - ongoing evaluation
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 - Male > 45 yrs
 - IHD in 1st degree relative
 - Current smoker
 - Hypertension
 - Cholesterol > 250 mg/dl
 - HDL < 35 mg/dl
 - Stent or prior intervention
 - Alcohol cirrhosis, pulmonary hypertension, hepatopulmonary disease – more frequent screening

Recommendations for All Organ Candidates

- Monitoring renal function
 - Liver high risk for developing hepatorenal syndrome
 - Heart candidates with CHF, or NYHA Class 111 or 1V
- Diabetic candidates
 - Peripheral vascular disease
 - Retinopathies
 - Nephropathy
 - CAD

Recommendations for All Organ Candidates

- Financial Screening every 3-6 months for commercial and Medicaid, annual for Medicare.
- Social work
 - annually ideally
 - every 3-6 months for at risk candidates

Recommendations for All Organ Candidates

- Cancer - American Cancer Society guidelines
 - Colon – flex sig/colonoscopy 2-5 yrs
 - Stool for occult blood x 3 annually
 - Uterine - pelvic exam annually
 - Cervical – PAP annually
 - Breast – exam annually, mammogram annually @ age 40 yrs
 - Prostate – PSA & digital exam after age 50 yrs
 - Oral-pharyngeal exam in smokers + alcohol users annually

Commencing program

- Size of waiting list
- Establish criteria for prioritization of re-assessment
 - Waiting time
 - Severity of illness
 - Known risk factors on initial evaluation
- Top 10-20 candidates in each blood type
 - Utilize match run
 - Utilize ‘dummy match run’ in Unet
 - MELD/PELD or LAS scores

Review of Re-evaluations of Waitlist

- Re-presentation at Candidate Selection Committee
 - Routine/ progression of disease/new onset of disease
- Develop delisting or deactivation criteria
 - More difficult for team to de-list a patient that decline listing initially
 - Palliative care team

Inactive Waiting List

- Develop process to track patient in inactive status
- Routine review of inactive list
- Communication with referring MD’s & patients
- Will become a compliance/regulatory process

Challenges

- New and unfamiliar practice for patients, especially kidney candidates
- Educate patients of new process
- Policy on how to handle no shows for re-evaluations
- Development of delisting criteria
- Resources
 - Time
 - Space
 - Personnel

Additional Tools to Consider

- Organ acceptance criteria
- Review wait list parameters in Unet
- Donor characteristics
 - Weight range
 - Age range
 - HCV+ or HbcAb +, CMV, crossmatch
 - Miles from donor to recipient

Additional Tools to Consider

- Refusal Codes/Refusal Rates report
 - Identify trends
 - Quality indicator for Tx Centers
- Access web site to check/verify deaths reported to SSDMF
<http://ssdi.genealogy.rootweb.com>
- HLA lab report to identify missed PRA sample submission
- Co-operation of Ref MD & Dialysis Units key
 - Communicate at every opportunity

Consent & Education

- Consent for ECD/SCD in kidney
- Informed Consent is a process
- Implement consent process at time of
 - Evaluation
 - Listing
 - Re-evaluation
 - Offer and/or OR
- Opportunity to provide education, improve patient understanding, adherence

Action Items

- Develop and implement an organ specific protocol for waitlist re-evaluation
- Review organ specific guidelines
- Develop de-listing criteria
- Implement a top 10-20 ABO priority review list
- Utilize <http://ssdi.genealogy.rootweb.com>
- Check who is reviewing
 - Unet reports of deceased patients on waiting list
 - Refusal codes for organ offers

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