ORGAN ALLOCATION POLICY IN TRANSPLANTATION

Dr. Minoo Adib
ORGAN ALLOCATION POLICY

• The process of determining how organs are distributed. Allocation includes the system of policies and guidelines, which ensure that organs are distributed in an equitable, ethical and medically sound manner.
قانون‌ها و سیاست‌های مربوط به تخصیص عضو پیوندی به بیماران نیازمند

چگونگی توزیع اعضای پیوندی در میان انبوه نیاز مندان پیوند عضو با رعایت:

• عدالت و انصاف. اخلاق و اصول صحیح پزشکی
• In **1967** the concept that **optimal tissue typing and matching** between donor and recipient would improve results of renal transplantation was proposed by Prof. Dr. Jon J. Van Rood

• founded the first and largest European Organ Exchange Organization fifty years ago.
Prof. Dr. Jon van Rood (immunologist)
Founding father Eurotransplant (1926-2017)

- Van Rood founded Eurotransplant in 1967
- Leiden University Medical Center
Eurotransplant (EU)

• 1970 Eurotransplant was active for 68 centers in six countries: Austria, Belgium, Luxembourg, West-Germany, the Netherlands and Switzerland. Eventually Switzerland withdrew from Eurotransplant, but in 1991 East-Germany joined in, followed in 1999 by Slovenia, in 2007 by Croatia and in 2013 by Hungary.

• 1996 new ETKAS introduced.
ETKAS

1996 new ETKAS introduced
Eurotransplant (EU)

- EU is an international non-profit organ exchange organization who is responsible for the allocation and international exchange of post mortem donor organs
European organ exchange organizations (EOEO)
ORGAN SHARING ORGANIZATIONS

• Eurotransplant
• UNOS
• British NHSBT
• Scandiatransplant.
ORGAN SHARING ORGANIZATIONS

• In addition to the support from the physicians, assistance from the police, ambulance services and airline companies is also indispensable for Eurotransplant.
ORGAN ALLOCATION POLICY

• each organ type has its own individual distribution policy, which reflect factors that are unique to each organ type:
HEART AND Lung

- Blood group
- Size of the donor
- Medical urgency
- Waiting time
- Distance from donor hospital (we use a radius from the donor hospital instead of regions)
- Pediatric status
KIDNEY

- Waiting time
- Medical urgency
- Donor/recipient immune system compatibility
- Prior living donor
- Distance from donor hospital
- Survival benefit
- Pediatric status
First step in match run

Before an organ is allocated, all transplant candidates on the waiting list that are incompatible with the donor because of blood type, height, weight and other medical factors are automatically screened from any potential matches. Then the computer system determines the order that the other candidates will receive offers.
“Match Run”

Factors affecting ranking may include:
- tissue match
- blood type
- length of time on the waiting list
- immune status - sensitization
- donor organ quality
- distance between the potential recipient and the donor
- degree of medical urgency (for heart, liver, lung and intestines)

Source: UNOS.org/TransplantLiving.org, 4/5/13
The urgency code on the renal waiting list is:

- **1:** High urgent.  
  - **HU:** Urgent 500+

- **2:** Highly immunized  
  - **HI:** PRA>85% 4+

- **3:** Immunized.  
  - **I:** PRA>6 and<85

- **4:** Transplantable.  
  - **T:** PRA<6

- **5:** not transplantable  
  - **NT**
ABO blood group rules (AM program)

- Donor BG: eligible recipient
  - A: A and AB
  - B: B & AB
  - O: O & others
  - AB: AB

- IDENTICAL BLOOD GROUP FOR OTHER RECIPIENTS
allocation factors

Eurotransplan allocation factors
The points according to HLA mismatches (PEDIATRIC*2)

- 0 HLA-A,B,DR = 400
- 1 HLA-A,B,DR = 333
- 2 HLA-A,B,DR = 266
- 3 HLA-A,B,DR = 200
- 4 HLA-A,B,DR = 133
- 5 HLA-A,B,DR = 66
- 6 HLA-A,B,DR = 0
Pediatric points

• < 6 years  100
• 6-11 year  33/3
• >11 <16  66/6

For pediatric transplant candidates the points for HLA-antigen mismatch are doubled.
Waiting time

• 0.09 points per day
• 33 points per year
geographic disparity

• 1: Local level 300
• 2: Equivalent level 300
• 3: Regional level 208
• 4: National level 104
• 5: International level 0
Mismatch probability

• The mismatch probability is a calculation of the probability of receiving a kidney offer with 0 and 1 broad HLA-A,-B or -DR mismatch based on 1000 kidneys offered taking into account the ABO blood group rules and the PRA screening using data from the Collaborative Transplant Study database.

• 0-100 points
• PERIOR LIVING DONOR  4  POINTS
• PRA>80%  4  POINTS
Ethnicity, gender, religion, and financial status are not part of the computer matching system.
Acceptable Mismatch (AM)

- Acceptable Mismatch (AM) program was proposed in 1996
The Eurotransplant Senior Program, also known as the ‘old for old’-program, started in 1999. Organs of donors of 65 years or older are allocated to recipients of the same age group, without taking into account the tissue characteristics.
Eurotransplant Senior Program (ESP)

• HLA-matching probably less important in older recipients
  – Reduced risk of repeated re-transplantation
  – Older patients might be less prone to rejection after transplantation
• Short ischemic time might reduce risk of graft loss from older donors
• For older recipients shorter waiting time might be especially important.
• IF NOT USED ALLOCATE THROUGH REGULAR ETKAS
Kidney Allocation

First to HU, HI patients and/or AM patients.

Next to 0, HLA-A, B, DR mismatch patients sorted according to their point score.

Next to the remaining recipients: sorted According to their point score.
The match list

• The match list is generated by a complicated computer algorithm that takes into account all medical and ethical criteria.
New KAS

• New KAS was approved by the organ procurement and transplantation network (OPTN) in June 2013 and subsequently implemented for clinical use starting on December 4th 2014.
EQUITY
UTILITY
Wait list time

- Wait list time starts from time of listing or date of initiation of dialysis, whichever comes first.
- The educated affluent candidates generally got listed as soon as glomerular filtration rate (GFR) is < 20 mL/min.
blood type

• The candidates with blood type B waited much longer as compared to blood type A/

• A2 AND A2B
The geographic disparity in different donor serving areas has worsened over time with the increased demand and limited supply of organs.
CPRA

• In old KAS Only 4 priority points were given for HLA sensitization for a PRA ≥ 80%

• Gradation of priority points given based on HLA sensitization for CPRA ≥ 20% range from 1-202, which can bring the recipient much higher on the list
• CPRA%                  points awarded

• 100                   202
• 99                    50
• 98                    24
• 97                    17
• 96                    12
• 95                    10
• ....                  ....
Longevity Matching

• allocation of best quality organs to wait-list candidates with the longest predictive survival
KDPI & EPTS

- Kidney donor profile index (KDPI) score (0%-100%)
  - <20% . 21-34%  35-85%  >85%

- Estimated Post Transplant Survival (EPTS) score (0%-100%)
  - 20% and 80%
The quality of organs

KDPI score (0%-100%) ;

• The quality of organs described based on the terms SCD, ECD and DCD kidneys

• **New KAS :**

  • The quality of organs assessed by a KDPI score (0%-100%) ; High discard rate existed for marginal ECD/DCD kidneys.

• DCD: Donation after circulatory death; ECD: Extended criteria donor; SCD: Standard criteria donor.
Kidney Donor Profile Index (KDPI)

KDPI Variables

- Donor age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- HCV Status
- DCD Status

Estimated Graft Survival Rates by KDPI

KDPI values now displayed with all organ offers in DonorNet®
The KDPI tells you how long a deceased donor kidney is expected to function relative to all of the kidneys recovered in the U.S. during the last year. Lower KDPI scores are associated with longer estimated function, while higher KDPI scores are associated with shorter estimated function. For example, a kidney with a KDPI of 20% is expected to have shorter longevity than 20% of recovered kidneys (i.e., longer function than 80% of recovered kidneys).
Figure 1: Estimated Graft Half Lives (years)

- Living Donor: 12.48 years
- KDPI 0-20%: 11.44 years
- KDPI 21-85%: 8.90 years
- KDPI 86-100%: 5.60 years
An Estimated Post Transplant Survival (EPTS) score is assigned to all adult candidates on the kidney waiting list and is based on four factors:

- Candidate time on dialysis
- Current diagnosis of diabetes
- Prior solid organ transplants
- Candidate age
EPTS score

• The EPTS score is not being used to rank-order patients, but rather to
• categorize patients into two broad groups: EPTS score is able to distinguish between expected outcomes among broad groups:
  • 0--20% and 21-80%.
  • EPTS score is able to distinguish between expected outcomes among broad groups
EPTS score

- A candidate's EPTS score can range from 0% to 100%. The candidates with EPTS scores of 20% or less will receive offers for kidneys from donors with KDPI scores of 20% or less before other candidates at the local, regional, and national levels of distribution. The EPTS score is not used in allocation of kidneys from donors with KDPI scores greater than 20%.
New KAS benefits

• The changes in organ allocation policy may lead to **INCREASE IN MEDIAN HALF-LIFE OF THE ALLOGRAFT AND INCREASE THE NUMBER OF TRANSPLANTS;** **THUS RESULTING IN BETTER UTILIZATION OF A SCARCE RESOURCE.** There could be unintended negative consequences which may become evident over time.
New kidney allocation system

Since a new kidney transplant system started Dec. 4, more kidneys are going to younger adults and patients with high levels of antibodies. Fewer are going to older patients.

Percentage of kidney transplant recipients:

- Age 18-49: 35.6%
- Age 50 or over: 59.3%
Overall Changes to Allocation System

- **Waiting time calculation**
  - Pre-registration dialysis time added

- **Candidate classification**
  - Estimated Post Transplant Survival Score (EPTS)

- **Kidney donor classification**
  - Replace SCD/ECD with Kidney Donor Profile Index (KDPI)
Waiting Time Points Priority

- Dialysis start date
- Date after registration that eGFR is at or below 20 mL/mn

*Peds begin accruing waiting time at listing regardless of clinical factors
## CPRA Match Classification Priority

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**CPRA greater than 98%**
Don’t Take Your Organs to Heaven. Heaven Knows We Need Them Here.
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*All categories in Sequence D are limited to adult candidates.*

New categories for highly sensitized candidates.
Points awarded to wait-listed candidates in the new kidney allocation system

• The waiting time 1 per year (1/365 per day)

• Pediatric candidates at time of match with 0-ABDR mismatch donor 4 (if child is 0-10 yr) 3 (if child is 11-17 yr)

• Pediatric candidate at time of match if KDPI < 35% 1

• Prior living donor 4

• Level of sensitization (cPRA ≥ 20%) 0-202

• Single HLA-DR mismatch with donor 1

• Zero HLA-DR mismatch with donor 2

• Candidate features Points awarded
The intent of longevity matching is to ensure that kidneys expected to function the longest are most often transplanted into those candidates expected to live the longest, thereby realizing the greatest benefit from kidney transplantation.

The EPTS will be used in tandem with the KDPI to introduce the concept of longevity matching into the new allocation system. The EPTS score will only be used in kidney allocation when the donor has a KDPI of 0-20%.

In other words, the EPTS will be used to prioritize candidates in only 20% of kidney allocations, while for 80% of allocations EPTS will not be used at all.
• UNet is the computer system used by the transplant center to calculate kidney, pancreas, and kidney/pancreas allocation scores for candidates in need of a transplant.
The Kidney Donor Risk Index (KDRI)

• The KDPI is a remapping of the KDRI onto a cumulative percentage scale, such that a donor with a KDPI of 80% has higher expected risk of graft failure than 80% of all kidney donors recovered last year and can be used to compute KDPI and KDRI for a hypothetical or actual donor. The calculations and
• The allocation system is:

• Objective: the match list is the same no matter which duty desk officer arranges the allocation
• Reproducible: the same question will lead to the same answer
• Transparent: every step in the process can be accounted for
• Valid: the system is based upon valid medical and ethical criteria that are supported by consensus within the transplant community.
• The match is based upon two general principles:

• Expected outcome
• Urgency (as determined by experts in an objective and transparent way)
• Furthermore, the following is taken into account:

• National organ balance - for Eurotransplant pursuits a reasonable balance in the exchange of organs between countries
• Waiting time
The allocation system

- The allocation system is:
  - Objective: the match list is the same no matter which duty desk officer arranges the allocation
  - Reproducible: the same question will lead to the same answer
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• Single HLA-DR mismatch with donor 1

• Zero HLA-DR mismatch with donor 2

• Candidate features Points awarded
• Standard-Criteria Donor
  The classic SCD is a 35-yr-old man who has no history of hypertension or diabetes and for whom the cause of death is a motor vehicle accident. In practice, all DDs who do not meet any of the criteria for an ECD and from whom donation occurred after brain death (donation after brain death [DBD]; see the Donation after Brain Death section) are considered as an SCD.

• Expanded-Criteria Donor
  An ECD is one who, at the time of death, is aged ≥60 or aged 50 to 59 yr and has any two the following three criteria: (1) Cause of death is cerebrovascular accident; (2) preexisting history of systemic hypertension; and (3) terminal serum creatinine >1.5 mg/dl. The criteria for the definition of ECD was based on the presence of variables that increased the risk for graft failure by 70% (relative hazard ratio 1.70) compared with an SCD kidney.

• Donation after Brain Death
  DBD describe a donor who had primary brain death in whom cardiac circulation and respiration remain intact or are maintained by medical measures, including mechanical ventilation, drugs, intra-aortic balloon pump, or extracorporeal machine oxygenation device. A DBD could be an ECD or SCD depending on whether the ECD/SCD criteria are separately fulfilled.

• Donation after Cardiac Death
  The donation after cardiac death (DCD) donor refers to the donor who does not meet the criteria for brain death but in whom cardiac standstill or cessation of cardiac function occurred before the organs were procured. The cessation of cardiac function could have occurred spontaneously or been initiated deliberately. The DCD donor was previously referred to as non–heart-beating donor. The DCD categories encompass four subgroups, depending on the circumstances and manner in which cardiac standstill occurred (Maastricht classification), but only two subtypes of DCD are in common usage (controlled DCD and uncontrolled DCD), which are defined next (12).

• Controlled DCD.
  The OPTN defines a controlled DCD (cDCD) as “a donor whose life support will be withdrawn and whose family has given written consent for organ donation in the controlled environment of the operating room.” The cDCD describes a situation in which the donor’s hemodynamic stability and respiratory function were maintained until the decedent is extubated in a controlled environment of the operating room or in the intensive care unit.

• Uncontrolled DCD.
  The OPTN defines uncontrolled DCD (uDCD) as “a candidate who expires in the emergency room or elsewhere in the hospital before consent for organ donation is obtained and catheters are placed in the femoral vessels and peritoneum to cool organs until consent can be obtained. Also, an uncontrolled Donation after Cardiac Death donor is a candidate who is consented for organ donation but suffers a cardiac arrest requiring CPR during procurement of the organs.”
Proposed Classifications: Very Highly Sensitized

- Candidates with CPRA >= 98% face immense biological barriers
- Current policy only prioritizes sensitized candidates at the local level.
- Proposed policy would give following priority

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<td>100%</td>
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<td>99%</td>
<td>Regional</td>
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<td>98%</td>
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- To participate in Regional/National sharing, review & approval of unacceptable antigens will be required
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New categories for highly sensitized candidates.
Modified Classification: Pediatric

- Current policy prioritizes donors younger than 35 to candidates listed prior to 18th birthday
- Proposed policy would
  - Prioritize donors with KDPI scores <35%
  - Eliminate pediatric categories for non 0-ABDR KPDI >85%
- Provides comparable level of access while streamlining allocation system
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**Continued priority pediatric candidates (now based on KDPI)**
Modified Classification: Local + Regional for High KDPI Kidneys

- KDPI >85% kidneys would be allocated to a combined local and regional list
- Would promote broader sharing of kidneys at higher risk of discard
- DSAs with longer waiting times are more likely to utilize these kidneys than DSAs with shorter waiting times
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*all categories in **Sequence D***

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**Proposed Regional Sharing**
Agree or disagree

1. Someone who has received 1 organ transplant should not be able to have another
2. Someone whose lifestyle (smoking, drinking, alcohol, obesity) has caused their organ failure should not get a transplant
3. If someone is on the donor register their organs should be taken for transplantation even if their family object
4. A person who has young children should be given a transplant before a single person
5. Someone in financial difficulty should be able to sell an organ such as a kidney
6. Prisoners with life sentences should not be given organ transplants
Removed Classification: Kidney Paybacks

- Current payback policy was evaluated and found to be:
  - Administratively challenging
  - Unfair in that it affected all candidates in an OPO even if only one center was responsible for accruing debt
  - Ineffective in improving outcomes of recipients
- Kidney paybacks would no longer be permitted.
- All payback credits and debts would be eliminated upon the implementation of the revised kidney allocation system.
PRIORITY WITHIN CLASSIFICATIONS
Points awarded to wait-listed candidates in the new kidney allocation system

- **Candidate features**
  - Points awarded
- The waiting time (date of listing with GFR < 20 mL/min, or date of initiation of dialysis)  
  - 1 per year (1/365 per day)
- Pediatric candidates at time of match with 0-ABDR mismatch donor  
  - 4 (if child is 0-10 yr) 3 (if child is 11-17 yr)
- Pediatric candidate at time of match if KDPI < 35% 1
- Prior living donor 4
- Level of sensitization (cPRA ≥ 20%) 0-202, see description
- Single HLA-DR mismatch with donor 1
- Zero HLA-DR mismatch with donor 2

**cPRA**: Calculated panel reactive antibody; **GFR**: Glomerular filtration rate; **KDPI**: Kidney donor profile index; **HLA**: Human leukocyte antigen.
Proposed Changes to Point System

- Candidates are rank-ordered according to points within each classification.

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<th>Proposed point changes for</th>
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<td>• HLA-DR</td>
<td>• Sensitized candidates</td>
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<tr>
<td>• Prior living organ donors</td>
<td>• Waiting time</td>
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<tr>
<td>• Pediatric candidates</td>
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Proposed Point Changes: Sensitization

- Current policy: 4 points for CPRA>=80%. No points for moderately sensitized candidates. Proposed policy: sliding scale starting at CPRA>=20%

(CPRA=98, 99, 100 receive 24.4, 50.09, and 202.10 points, respectively.)
Proposed Point Changes: *Waiting Time*

- Current policy begins waiting time points for adults at registration with:
  - GFR\(\leq 20\) ml/min
  - Dialysis time
- Proposed policy would also award waiting time points for dialysis time prior to registration
  - Better recognizes time spent with ESRD as the basis for priority
- Pre-emptive listing would still be advantageous for 0-ABDR mismatch offers
SIMULATED POLICY RESULTS
First transplants outside the Eurotransplant area
1954: living donor kidney (USA)
1963: deceased donor kidney (Leuven, Belgium)
1966: pancreas/kidney (USA)
1967: heart (South Africa)
1967: liver (USA)
   1972: liver (Hannover, Germany)
   1979: pancreas (Munich, Germany)
   1979: pancreas/kidney (Munich, Germany)
1981: heart and lung (USA)
1983: single lung (Canada)
1986: double lung (USA)
1987: intestine (USA)
   1987: domino heart donor (Vienna, Austria)
1988: split liver (USA)
1989: living donor liver (USA)
   1989: intestine (Innsbruck, Austria)
   1989: double lung (Hannover, Germany)
1990: living donor lung (USA)
1991: living donor liver (Hamburg, Germany)
   1992: pancreas islets (Gießen, Germany)
1996: domino liver donor (Ghent, Belgium)

First transplants inside the Eurotransplant area
1954: living donor kidney (USA)
   1963: deceased donor kidney (Leuven, Belgium)
1966: pancreas/kidney (USA)
1967: heart (South Africa)
1967: liver (USA)
   1972: liver (Hannover, Germany)
   1979: pancreas (Munich, Germany)
   1979: pancreas/kidney (Munich, Germany)
1981: heart and lung (USA)
1983: single lung (Canada)
1986: double lung (USA)
1987: intestine (USA)
   1987: single lung (Innsbruck, Austria)
   1987: domino heart donor (Vienna, Austria)
1988: split liver (USA)
1988: split liver (Hannover, Germany)
1989: living donor liver (USA)
   1989: intestine (Innsbruck, Austria)
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1990: living donor lung (USA)
1991: living donor liver (Hamburg, Germany)
   1992: pancreas islets (Gießen, Germany)
   1996: domino liver donor (Ghent, Belgium)
Summary

- New system forecasted to result in:
  - 8,380 additional life years gained annually
  - Improved access for moderately and very highly sensitized candidates
  - Improved access for ethnic minority candidates
  - Comparable levels of kidney transplants at regional/national levels
Participate in Policy Development

- Submit comments online: optn.transplant.hrsa.gov
- Access webinar schedules
- Download educational materials

Public comment period ends December 14
eurotransplant.org

Eurotransplant Network Information System (ENIS)

- Eurotransplant Network Information System manual

- www.eurotransplant.org
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