

## An Overview of Organ Allocation The OPTN, Geography, & Policy

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## Disclosures

- Pfizer – grant support
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## Overview

- NOTA and the OPTN
- Evolution and Geography
- Policy Development



## Evolution of Regulation

- 1980's – transplantation grows with success of cyclosporine
- 1983-1984 – Unregulated transplant system publicized and congress intervened
- 1984 Congress passes National Organ Transplant Act (NOTA)



## Transplant Policies

- NOTA established:
  - Task Force on Organ Procurement and Transplantation
  - Organ Procurement and Transplantation Network (OPTN) (contract held by UNOS since 1986)
  - Scientific Registry of Transplant Recipients (SRTR) (contract held by UNOS '83-'03, Arbor Research '03-'10 and Minnesota Medical Research Foundation '10-present)
- Outlawed buying and selling of organs (“valuable consideration”)



## OPTN

- Improve the effectiveness of deceased donor organ procurement and distribution
- Increase patient access to state-of-the-art transplantation technology
- Maintain and improve the skills of hospitals and professionals involved in organ procurement and transplantation
- Assure quality control by collection, analysis and publication of data



## OPTN Goals

- Improve the system for sharing organs so as to:
  - Facilitate donor and recipient matching, based on specific criteria established for each organ
  - Improve transplantation outcomes
  - Decrease the wastage of organs



## OPTN Goals

- Maintain a computer-based organ allocation system and an Organ Center:
  - 24-hour transplant program access to the donor/recipient matching system
  - Collect data on transplant recipients from the time of the transplant until graft failure or patient death



## Definitions

- OPO: Organ Procurement Organization
- Transplant center: Hospital that is an OPTN member
- Transplant program: A transplant center may have more than one transplant program
- OPTN waiting list: computerized list of patients waiting to be matched with a specific donor



## Geography

- To achieve efficiency in the system (minimize cold ischemic times of organs, etc.) and promote donation in local areas allocation in most cases is:
  - Local
  - Regional
  - National



## Definition of Local

- Local unit (the transplant list) is the OPO in most cases (also known as donor service area or DSA):
  - The kidney sharing unit consists of all transplant programs served by an OPO (usually multiple programs)
  - May be several different sizes
- Alternative local unit (ALU) requests have been granted on occasion
  - The kidney sharing unit may comprise more than one OPO
  - Dissolved in the new Kidney Allocation System initially, but requests may be considered after the first year



## NOTA & OPOs

- Qualified organizations
  - (A) is a nonprofit entity
  - (II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations
  - (F) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs
  - (A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donation

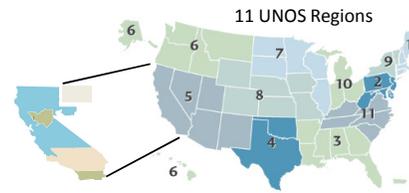


## Examples of Different Sized Local Units for Kidney Sharing

Examples of Different Sized Local Units for Kidney Sharing



## Regions



Donor Service Areas (DSAs) and Organ Procurement Organizations (OPOs)



## Geographic Disparities in Allocation

- Given the regionality of organ allocation, disparities in access to transplant based on geography have developed and worsened over time
- Not addressed for many years, now an issue being addressed by UNOS Committees on an organ-specific basis
- Starts with defining metrics of equity (MELD score, LAS score, waiting time, etc.)



## Geographic Disparities in Allocation

- Reasons for disparities are complicated
  - Supply vs. Demand
  - OPO efficiency
  - Center specific organ acceptance patterns
  - Center specific candidate listing patterns
- Methods to achieve equity are not yet defined but will likely involve re-districting



## Organization and Policy Making for the OPTN

- 11 UNOS Regions each have semi annual meetings and voting rights
- The OPTN Board of Directors sets policy within the guidelines of the “Final Rule,” which was effective March 16, 2000 and established a regulatory framework for the structure and operations of the OPTN
- OPTN policies that are meant to be binding on OPTN members are submitted to the Secretary of HHS for final approval



## OPTN Board of Directors

- Officers
- Regional representatives
- Patient and donor family representatives
- Voluntary health organization representatives
- Medical/scientific organization representatives
- Histocompatibility lab, OPO and transplant coordinator representatives
- Approximately 50% physicians and surgeons



## Membership in the OPTN

- Congress has ruled that it is mandatory for every transplant center to belong to the OPTN and to abide by its rules and regulations
- Non-compliance with OPTN rules and regulations can lead to withholding of all Medicare funding for that hospital



## OPTN Data Collection

- All data is collected via an online Web application called UNet<sup>SM</sup>
- Transplant programs, histocompatibility labs and OPO's use UNet<sup>SM</sup> for the following:
  - Manage lists of waiting patients
  - Complete electronic data collection forms
  - Add donor information and run donor-recipient matching lists
  - 26 different forms contain 3,500 data fields



## OPTN Data Collection

- Mandatory to submit data to the OPTN at the designated times
  - Pretransplant data
  - Transplant data
  - 6 months posttransplant and on every transplant anniversary
  - Malignancy forms



## Allocation of thoracic organs

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Medical Director, Heart Transplant Program  
University of Utah School of Medicine  
Director, ISHLT Transplant Registry

Disclosures: None



## UNOS waiting list priority

- Initial algorithms:
  - Match compatible organs
  - Base priority heavily on time on waiting list
  - Allocate organs locally first



## Change in OPTN rules - 1998

- Broader geographic sharing of organs
- Reduce importance of waiting time
- Use objective medical criteria to establish medical urgency for transplant

Department of Health and Human Services. OPTN;  
Final Rule. In: Federal Register 42 CFR, Part 121,  
October 20, 1999: 56649–56661



## Lung allocation before 2005

- Heavily based on time on waiting list
- Extra 90 days provided to candidates with idiopathic pulmonary fibrosis



## Development of Lung Allocation Score (LAS)

- Goals:
  - reduce the number of waiting list deaths
  - increase transplant benefit for recipients
  - efficient and equitable allocation



## Predictors of mortality

**Table 1:** Results of multivariable diagnosis-specific models for waiting list mortality

COPD	CF	IPF	PPH
In ICU/hospital	In ICU/hospital	In ICU/hospital	In ICU/hospital
Steroid dependency $\geq 5$ mg/day	Steroid dependency $\geq 5$ mg/day	On ventilator	On ventilator
2 or more i.v.-treated pulmonary sepsis episodes within last 12 months	Diabetes	6-minute walk distance <150 ft	Steroid dependency $\geq 5$ mg/day
Alpha-1 vs. other COPD	Wedge pressure	Wedge pressure	Wedge pressure
FEV1 % predicted	FVC % predicted	FVC % predicted	
O <sub>2</sub> requirement at rest	Cardiac output	PA systolic	
BMI	BMI	Weight	
Age		Age	

**Table 2:** Results of multivariable diagnosis-specific models for posttransplant mortality within 1 year

COPD	CF	IPF	PPH
In ICU/hospital at transplant	Drug-treated peptic ulcer disease prior to listing	On mechanical support at transplant	In ICU at transplant
Older age		History of coronary artery disease at listing	Single lung transplant
Center volume		pCO <sub>2</sub> at transplant	Higher weight

Source: OPTN.

Eagan TM et al.  
Am J Transplant. AJT 2006 (6)



## Factors used to calculate LAS

Factors used to predict waiting list survival

FVC (% predicted)  
PA systolic pressure  
O<sub>2</sub> required at rest (L/min)  
Age at offer  
Body mass index (BMI)  
NYHA functional status  
Diagnosis<sup>1</sup>  
Six-minute walk distance <150 feet  
Continuous mechanical ventilation  
Diabetes

Factors used to predict posttransplant survival

FVC (% predicted)  
PCW mean pressure  $\geq 20$  mmHg  
Continuous mechanical ventilation  
Age at transplant  
Serum creatinine (mg/dL)  
NYHA functional status  
Diagnosis<sup>1</sup>

<sup>1</sup> Group A, obstructive lung disease; Group B, pulmonary vascular disease; Group C, cystic fibrosis and immunodeficiency disorders; Group D, restrictive lung disease.

Source: SRTR.

LAS implemented in 2006  
Patients  $\geq 12$  years



## Heart allocation - 1988

- Medical urgency:
  - Status 1- MCS or ICU & inotropic support
  - Status 2- all others
- Time on waiting list
- Local allocation first



## Medical urgency change - 1999

- Aimed at better stratifying risk of mortality on the waiting list
  - Status 1A
  - Status 1B
  - Status 2



## Expanded regional sharing - 2006

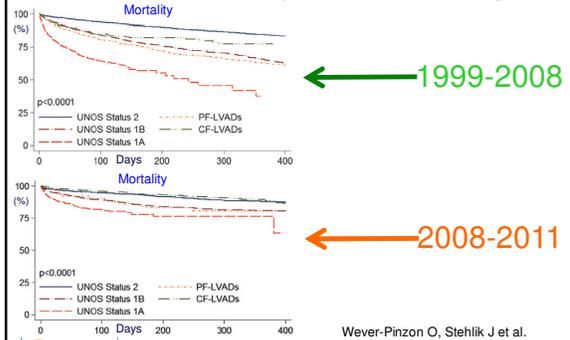
**Table 1** Sequence of Adult Heart Allocation<sup>a</sup>

Before July 2006	After July 2006
Local	Local
1. Status 1A candidates	1. Status 1A candidates
2. Status 1B candidates	2. Status 1B candidates
3. Status 2 candidates	Zone A
Zone A	3. Status 1A candidates
4. Status 1A candidates	4. Status 1B candidates
5. Status 1B candidates	5. Status 2 candidates
Zone B	Zone B
6. Status 1A candidates	6. Status 1A candidates
7. Status 1B candidates	7. Status 1B candidates
Zone A	Zone A
8. Status 2 candidates	8. Status 2 candidates
Zone B	Zone B
9. Status 2 candidates	9. Status 2 candidates
Zone C	Zone C
10. Status 1A candidates	10. Status 1A candidates
11. Status 1B candidates	11. Status 1B candidates
12. Status 2 candidates	12. Status 2 candidates



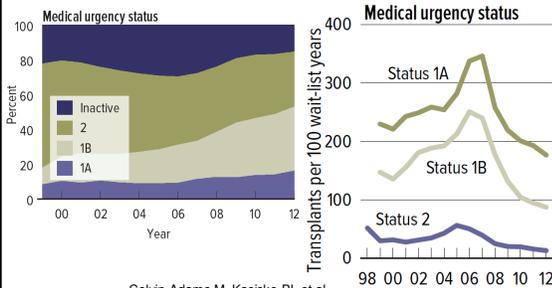
Nativi JN, Stehlik J. J Heart Lung Transplant. 2011; 30(8)

## Reduced mortality on the waiting list



Wever-Pinzon O, Stehlik J et al. Circulation 2013 Jan 29;127(4)

## Change in transplant rate



Colvin-Adams M, Kasiske BL et al. Am J Transplant. 2014 Jan; 14

## Change in status at transplant distribution and waiting times

UNOS Status	Transplanted in status	Median waiting time
1A	64%	78 days
1B	31%	224 days
2	5%	618 days

Data for calendar year 2012

Stehlik J, Stevenson LW, Mehra MR et al. J Heart Lung Transplant. 2014 Oct;33(10)



## Conclusion

- Organ allocation algorithms evolved to minimize waitlist mortality and maximize transplant benefit
- Changes in organ allocation need to be responsive to changes in clinical care of patients with advanced organ disease

