Updated Changes to the UNOS Pediatric Heart Transplant Listing Criteria

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Until every child is well℠

Objectives

- Learner will describe the new UNOS pediatric heart transplant listing criteria
- Learner will discuss the rationale behind the recent UNOS pediatric heart transplant listing criteria changes

Pediatric Heart Transplantation: current state

30 Years

>50 centers

350+ transplants / year

3 decades have seen improvement in outcomes, management and risk surveillance

Pediatric Heart Transplantation: The Problem- waitlist mortality

- Pediatric heart transplant faces highest waitlist mortality of all organs
- Between 1999-2006, 533 (17%) patients died on waitlist
- majority of patients in the highest listing criteria (UNOS status 1A)
- 2009, Almond study: high variability of waitlist mortality in 1A listings, highest mortality in infants, CHD, ECMO, ventilatory support

Closer look at the variables

	Univariate Predictors		
Variable	Survived (N=2565)	Died (N=533)	P Value‡
Age categories			
<1	883 (78%)	250 (22%)	<0.001
1-5	594 (84%)	115 (16%)	
6-11	394 (86%)	62 (14%)	
12-17	694 (87%)	106 (13%)	
Weight categories			
<10	1059 (79%)	285 (21%)	<0.001
10-19	441 (84%)	87 (16%)	
20-39	415 (87%)	63 (13%)	
40-59	350 (90%)	41 (10%)	
≥60	276 (85%)	47 (15%)	
Female (%)	1127 (83%)	232 (17%)	0.74
Non-white (%)	1020 (79%)	274 (21%)	<0.001

	Univariate Predictors		
Variable	Survived (N=2565)	Died (N=533)	P Value‡
UNOS Status			
1A	1479 (79%)	395 (21%)	<0.001
1B	374 (89%)	44 (11%)	
2	712 (88%)	94 (12%)	
Cardiac Diagn.			
CHD	1151 (77%)	343 (23%)	<0.001
Cardiomyopathy	1064 (90%)	122 (10%)	
Myocarditis	152 (85%)	26 (15%)	
Other	198 (83%)	42 (18%)	
Prostaglandin	143 (75%)	48 (25%)	<0.001
Hemo. Support			
ECMO	245 (69%)	112 (31%)	<0.001
Ventilator	451 (75%)	152 (25%)	
Other	1869 (87%)	269 (13%)	

The Response:
UNOS and Transplant Centers

- Develop organ allocation policies and definitions to prioritize organ allocation to most critically ill patients

Transplant Centers:

- Individual center response to successfully transition a patient to heart transplant (ie expand listing to high risk, ABO incompatible)

UNOS: The responsibility- equitable and current listing definitions

UNOS Goals

- Transparent, regulated process
- Equal expectations regardless of area of residence
- Keeping up with advancement in medical and surgical heart failure strategies

History

- 1980's UNOS created a policy review committee consisting of cardiologists and cardiac surgeons, currently named Thoracic Organ Transplant Committee
- Objectives: develop and monitor heart and lung organ allocation policies and review issues related to procurement and transplant, including the scientific, medical and ethical aspects

The process

UNOS creates rules and policies that govern the transplant centers, organ procurement organizations (OPO's) and histocompatibility labs in US

Committees developed to divide the policy initiatives into organ specific areas

Goal: collaborative policy development process promotes equity among patients waiting for organs and allows policy modification to reflect current science and medical practice

Historical changes

1980's

- 2 Status' (1 and 2): pediatric and adult
- Defined by location of patient (ICU vs home)
- Local Regional Review Board (RRB) grants exceptions

1990-2000's

- Multiple tiered system (1A, 1B, 2)
- Definitions for pediatrics and adult listings
- Definition based on level of care, not location
- Response to new HF management strategies (VAD)
- Sensitization exceptions
- Allocation changes: Adolescent donors (18 year or younger) offered to pediatric list first
- Oversight: Every 14 day submissions of 1A justification forms

Definitions

UNOS 1 and 2 (before 1999)
Defined by location of patient

- UNOS status 1
  - in ICU
- UNOS status 2
  - Anywhere else

UNOS 1A, 1B and 2 (1999-2016)
Defined by medical needs of patient

- UNOS status 1A
  - Less than 6 months of age with CHD and reactive pulmonary disease
  - Single high dose inotrope (Milrinone 0.5mcg/kg or more; Dopamine 7.5mcg/kg or Dobutamine 7.5mcg/kg or more
  - Multiple low dose intropes (any combination of inotropes)
  - Intubated
  - Mechanical support (ECMO/VAD)
  - *1A by exception: life exepctancy <14 days, life threatening arrhythmias*
- UNOS status 1B
  - Less than 6 months and does not meet 1A criteria
  - Single low dose inotrope
  - Failure to thrive
- UNOS status 2
  - All others

Current 2016 UNOS Listing changes: Key points

Reducing waitlist mortality to highest risk groups (infants, CHD, high level of support)

Granular definitions of medical needs

Location of patient is brought back into definitions (ie: admitted to listing center)

Current UNOS definitions

UNOS 1A:

- Definition: Patient under the age of 18 years at the time of registration and meets one of the following criteria:
- Continuous mechanical ventilation and inpatient at the listing hospital
- Intraortic balloon pump and inpatient at the listing hospital
- Ductal dependent pulmonary or systemic circulation with ductal stent in place or continuous infusion to keep the duct open and inpatient at the listing hospital (no age requirement)
- Congenital heart disease with multiple low dose inotropes or 1 high dose inotrope and inpatient at the listing hospital
- Mechanical circulatory support (does not require hospitalization)
- Valid for up to 14 days, renewal process unchanged; downgraded to 1B by system if not renewed at 14 days.
- 1A Exception – hospitalized at listing hospital and MD feels that medical urgency is comparable to other 1A candidates/requirements. Valid for 14 days.

Current UNOS definitions *(cont.)*

UNOS 1B:

- Definition: Patient under the age of 18 years at the time of registration and meets one of the following criteria:
- Continuous infusion of 1 or more inotropes and does not qualify for 1A (can be home; CDMY)
- <1yr of age at initial registration with restrictive or hypertrophic cardiomyopathy

UNOS 2:

- Definition: Patient under the age of 18 years at the time of registration and does not meet status 1A or 1B criteria but is suitable for transplant.

Changes to Allocation

1980-1990's

- Regional list exhausted first

1996-current

- 1996: pediatric donors to pediatric recipients
- 1999: sensitization considerations, highly sensitized patients petitioned to RRB to move to the top of the list for negative crossmatches
- 2006: organ offered in region for 1A then 1B, then out of region to 1A then 1B, then back to primary region for status 2

Listing centers response to problem

- ABO incompatible listings
- Use of high risk donors

Future Needs

- Review of impact of new definitions
- Ongoing work to support high risk listed patients
- Quicker response to changes needed to definitions and allocation

Questions?