

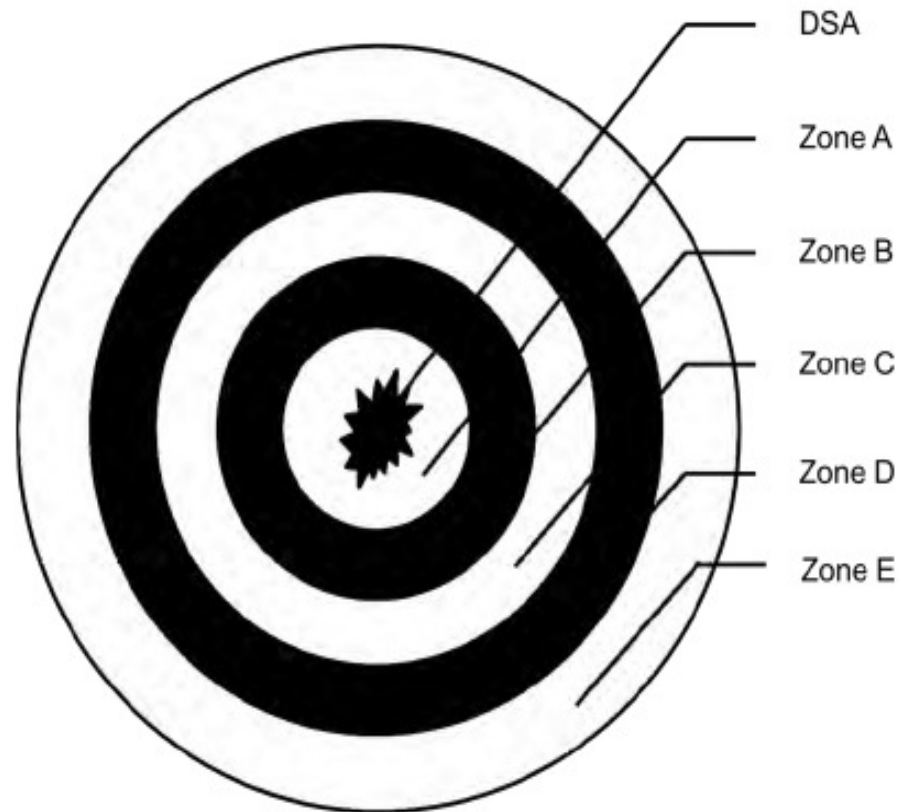
OPTN/UNOS- Thoracic Organ Transplantation Committee: Proposed Modifications to Adult Heart Allocation

- 1) Develop additional urgency stratifications based on relative waiting list mortality rates for all adult heart candidates
- 2) Modify the geographic sharing scheme to provide the most medically urgent candidates access to donors from a broader geographic area

What problems is the proposal attempting to solve?

- 1) Too many status 1A candidates
- 2) Too many exception requests required
- 3) Increased use of MCSDs not accommodated by current system
- 4) Geographic sharing scheme is inequitable

Figure 1: Zones Used for Thoracic Organ Allocation



Each zone = 500 mile radius

Status	Proposed Criteria
1	<ul style="list-style-type: none"> i. ECMO ii. Mechanical ventilation iii. Non-dischargeable BiVAD or RVAD iv. Mechanical circulatory support with life-threatening ventricular arrhythmia
2	<ul style="list-style-type: none"> i. Intra-aortic balloon pump ii. Acute circulatory support device iii. Ventricular tachycardia/ventricular fibrillation, mechanical support not required iv. Mechanical circulatory support with device malfunction/mechanical failure v. Total artificial heart vi. Dischargeable BiVAD or RVAD
3	<ul style="list-style-type: none"> i. LVAD for up to 30 days ii. Status 1A exception iii. Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring iv. Mechanical circulatory support with device-related complications other than infection, thromboembolism, device malfunction/mechanical failure or life-threatening ventricular arrhythmia v. Mechanical circulatory support with device infection vi. Mechanical circulatory support with thromboembolism
4	<ul style="list-style-type: none"> i. Diagnosis of congenital heart disease (CHD) with: <ul style="list-style-type: none"> a. Unrepaired/incompletely repaired complex CHD, usually with cyanosis b. Repaired CHD with two ventricles (e.g., TOF, TOGV) c. Single ventricle repaired with Fontan or modifications ii. Diagnosis of ischemic heart disease with intractable angina iii. Diagnosis of hypertrophic cardiomyopathy iv. Diagnosis of restrictive cardiomyopathy v. Stable LVAD candidates after 30 days vi. Inotropes without hemodynamic monitoring vii. Diagnosis of amyloidosis viii. Retransplant ix. Status 1B exception
5	Combined organ transplants: heart-lung; heart-liver; heart-kidney
6	All remaining active candidates
7	Inactive/not transplantable



Heart and Lung Allocation in Europe

Luciano Potena, MD PhD
Heart and Lung Transplant Program University of Bologna



CUTTING EDGE OF
TRANSPLANTATION

AST | AMERICAN SOCIETY OF
TRANSPLANTATION

RESOLVING THE ORGAN SHORTAGE



PRACTICE |



POLICY |



POLITICS

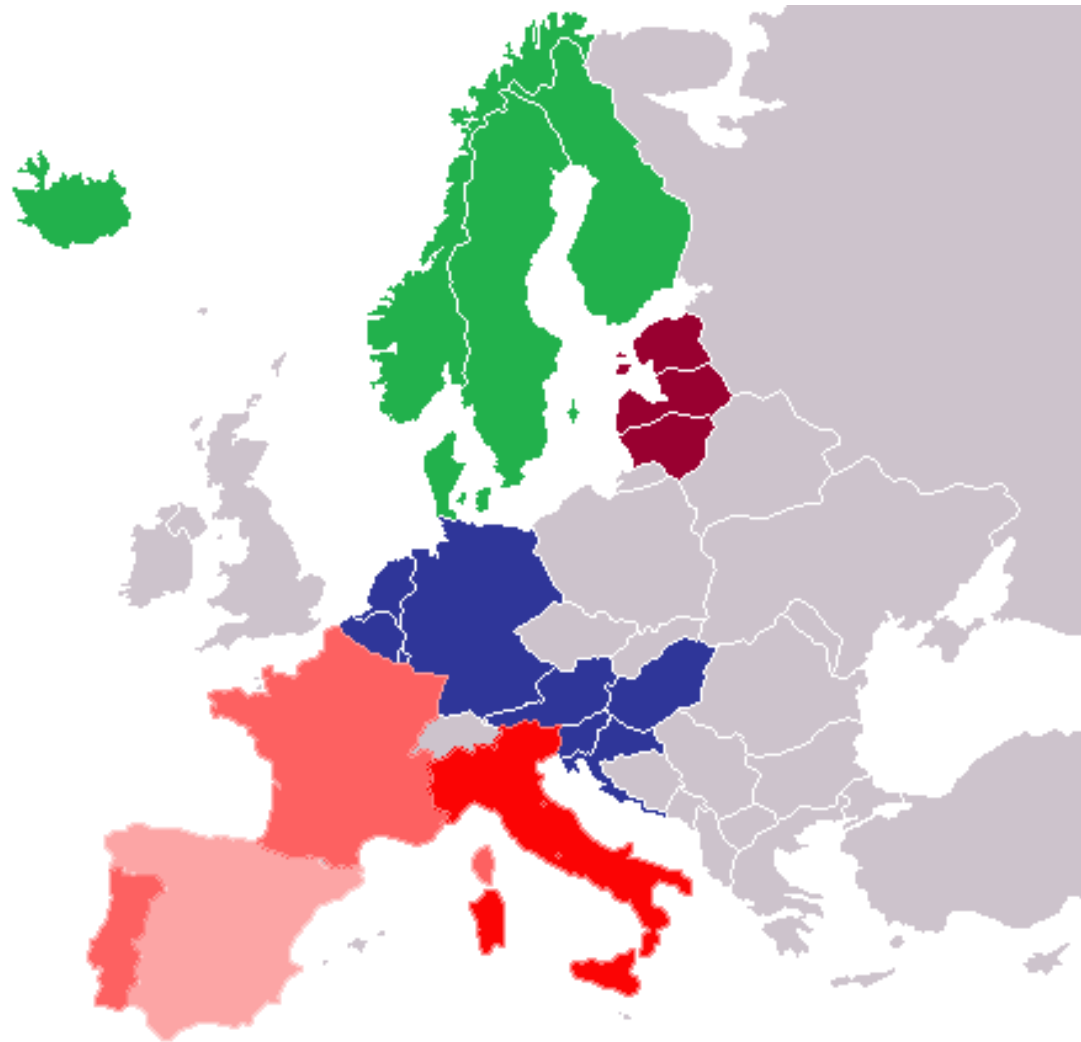
FEBRUARY 25-27, 2016 • PHOENIX, ARIZONA

Conflict of Interest Disclosure

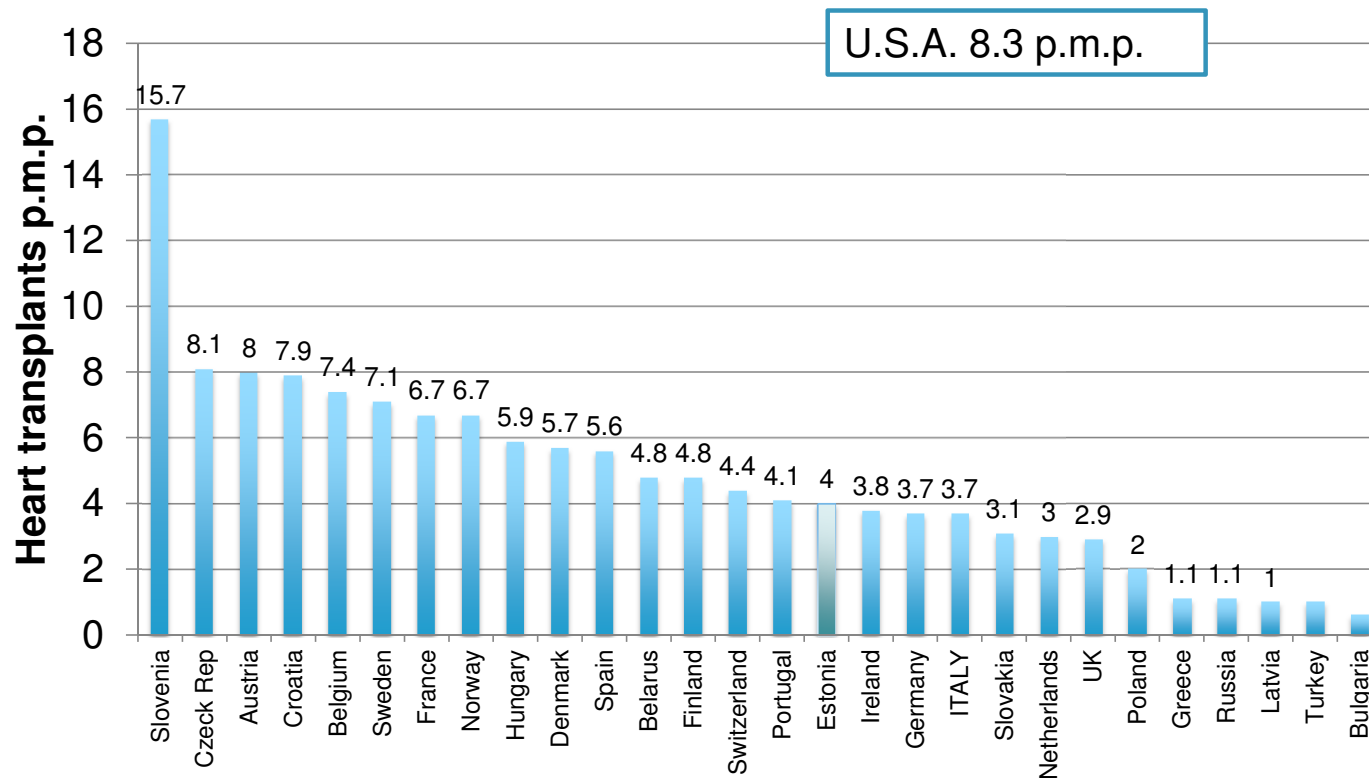
- I received Advisory board fees from Diaxonhit and Biotest
- My institution received research support from Novartis and Qiagen
- No off label drug or device use is mentioned in this presentation



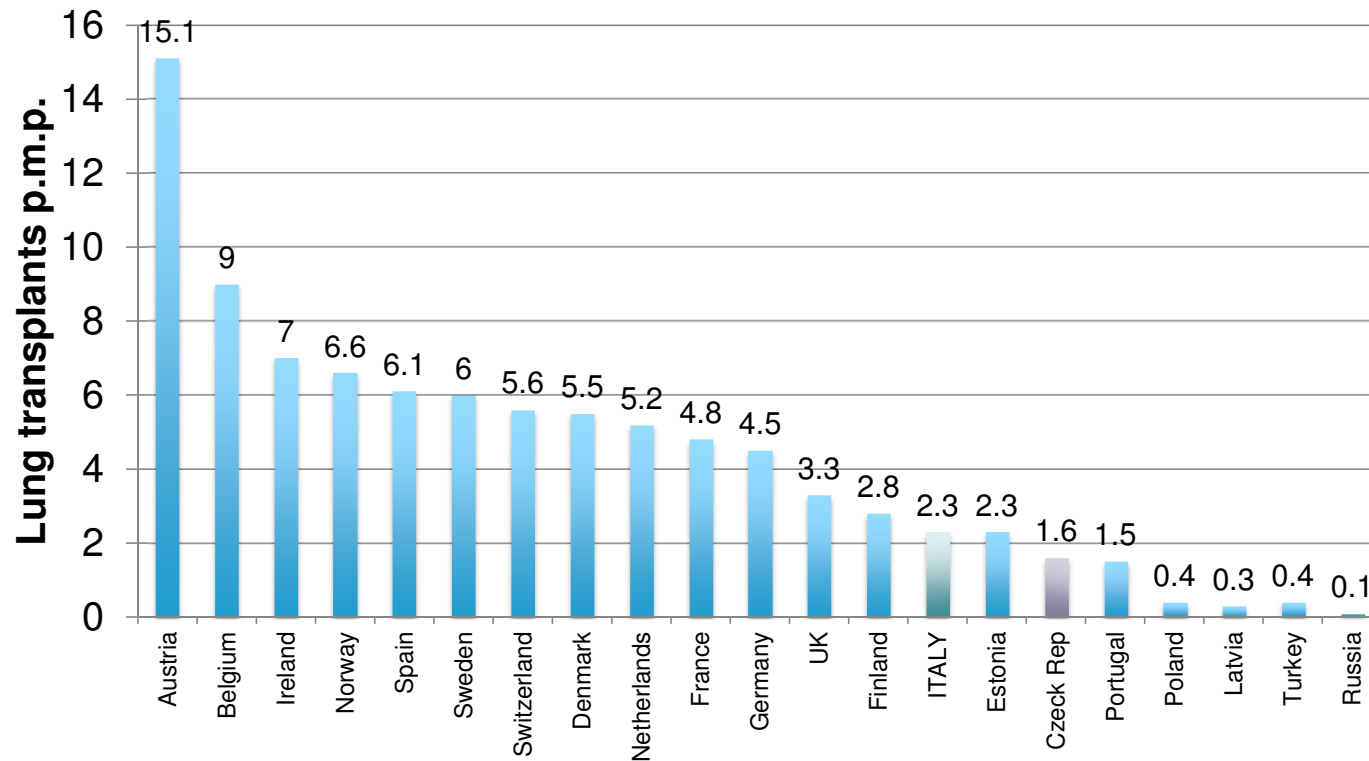




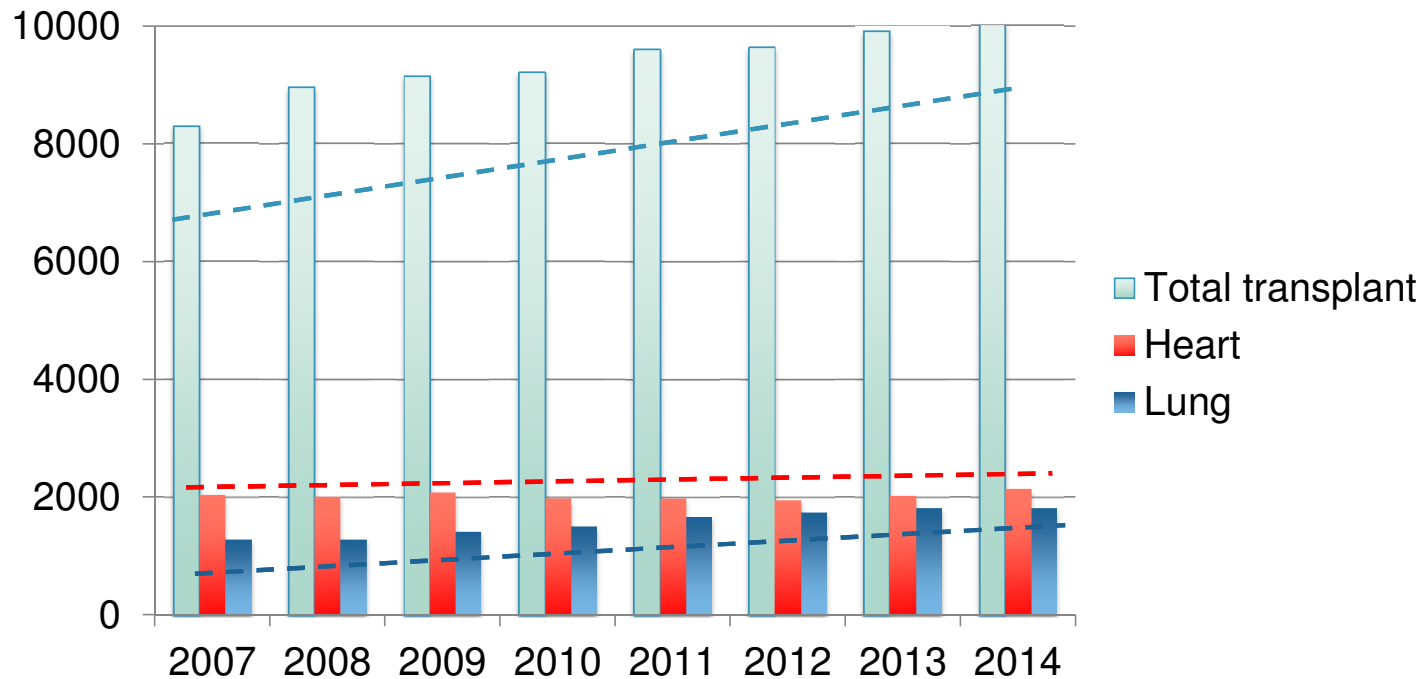
Heart Transplant in Europe in 2014 n=2146



Lung Transplant in Europe in 2014 n=1822

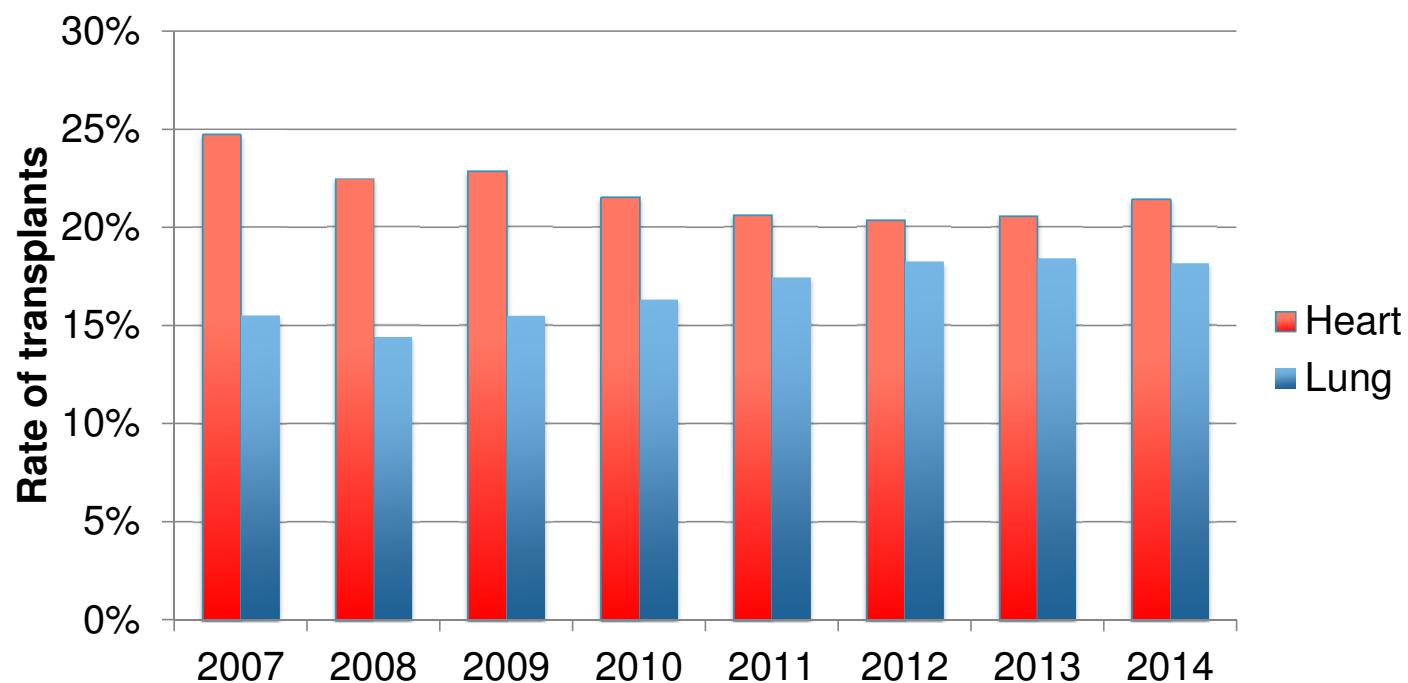


8-year trend of heart and lung transplant in Europe



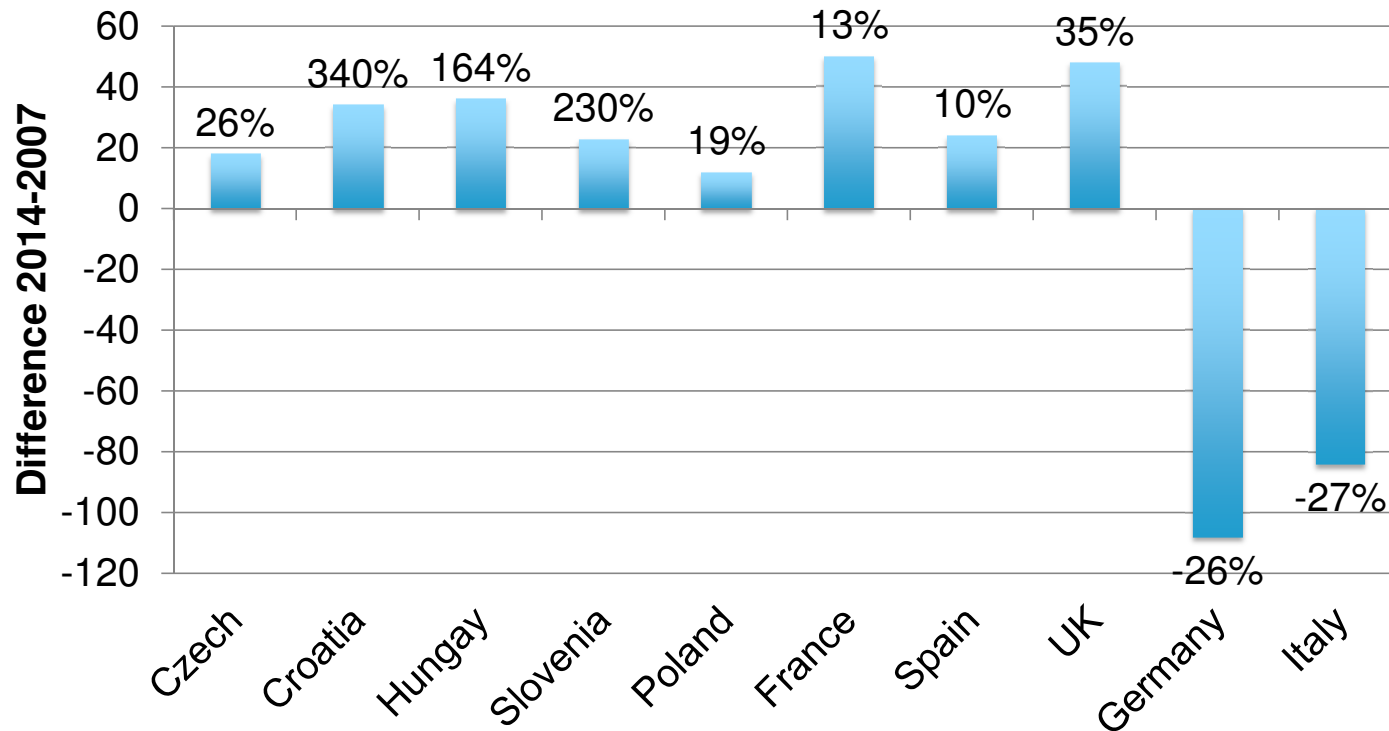
Data from the Council of Europe – 27 countries

Rate of thoracic transplants over the total

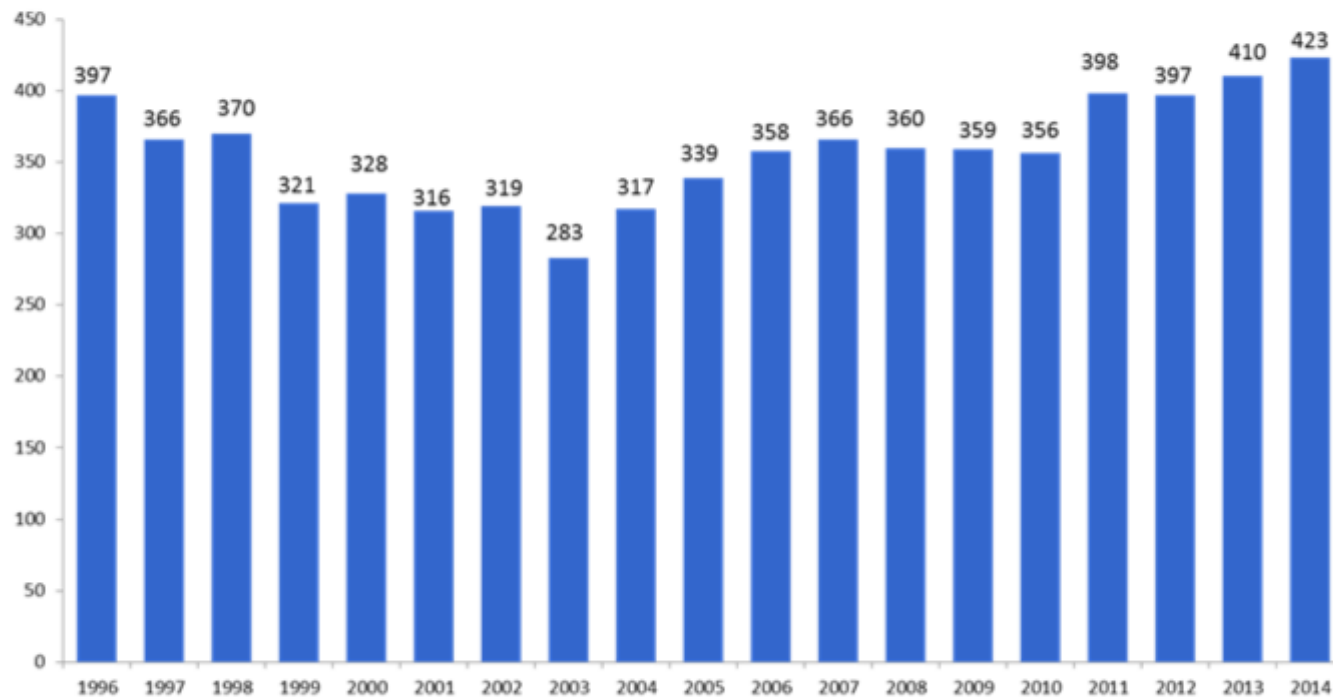


Data from the Council of Europe – 27 countries

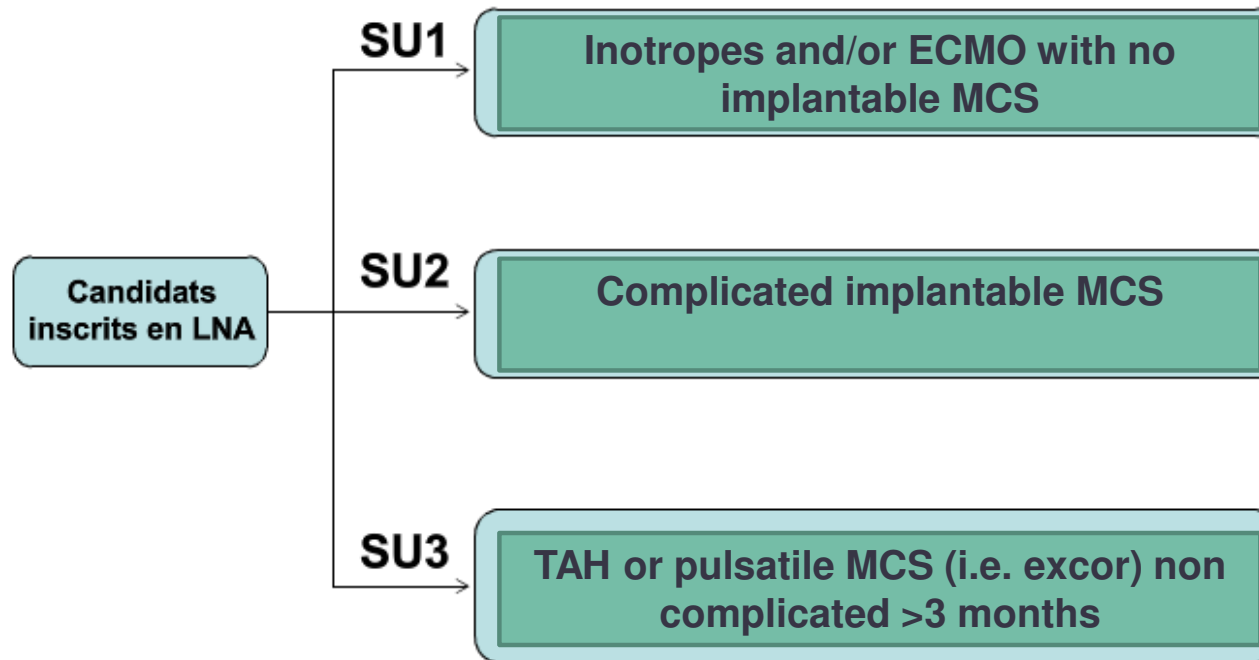
Variability in HT numbers



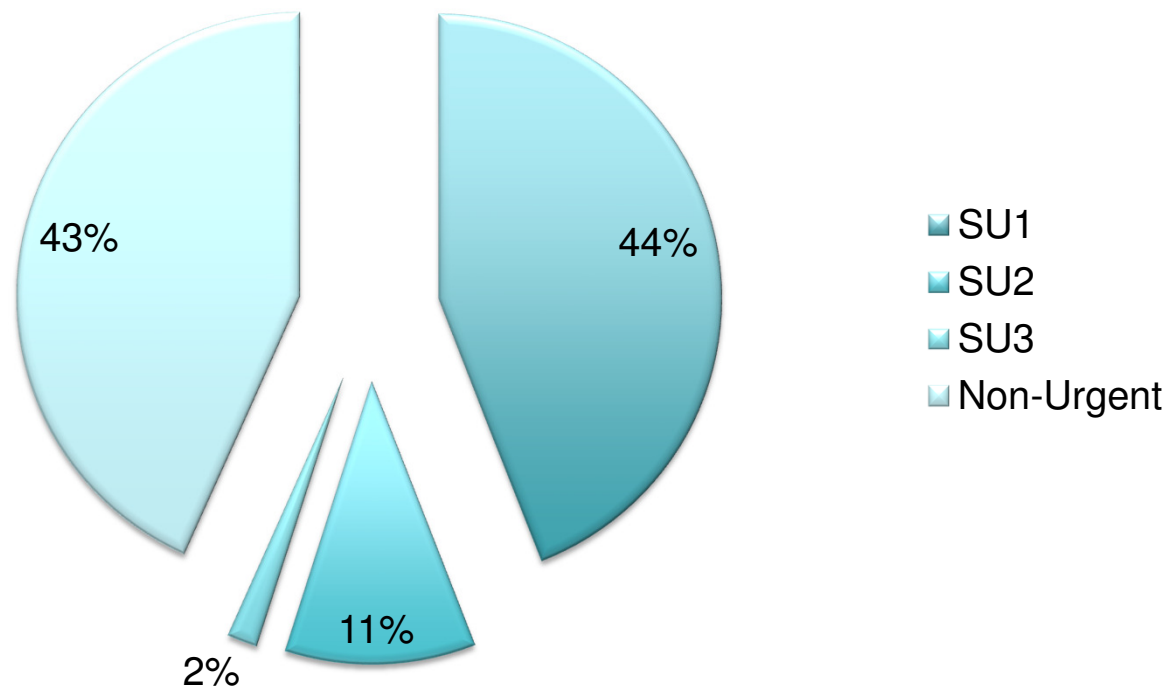
Numbers of heart transplants in France



Rules of priority allocation in France



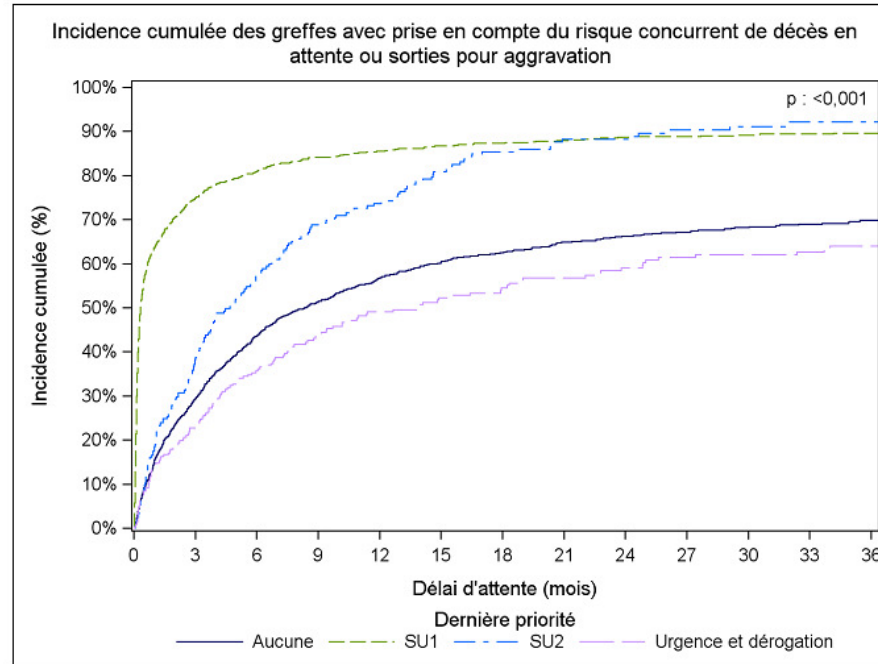
Rate of urgent cases over the total in 2014 (n= 423)



Cumulative incidence of transplant according with priority

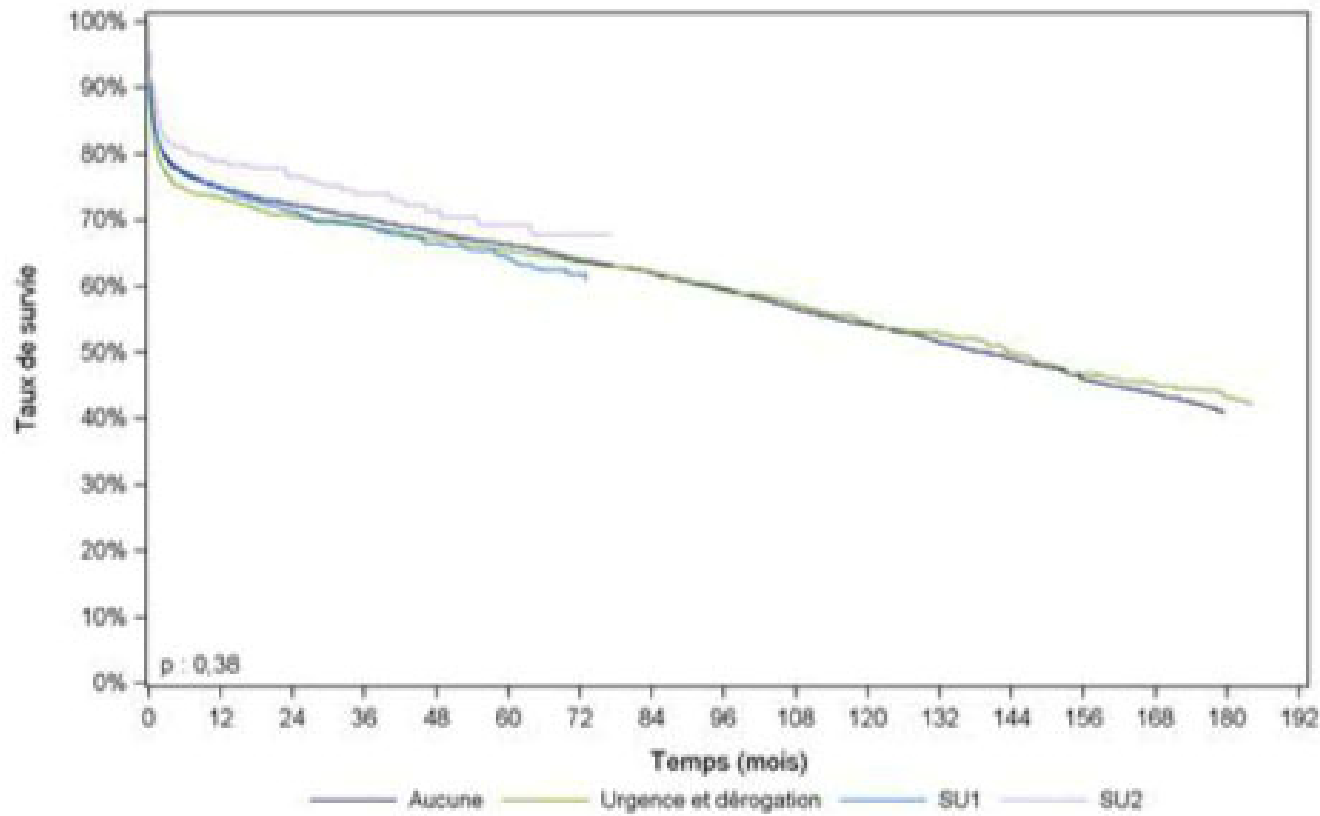
Mortality/deterioration while on SU1= 5%

Overall 1 y mortality on WL:24%

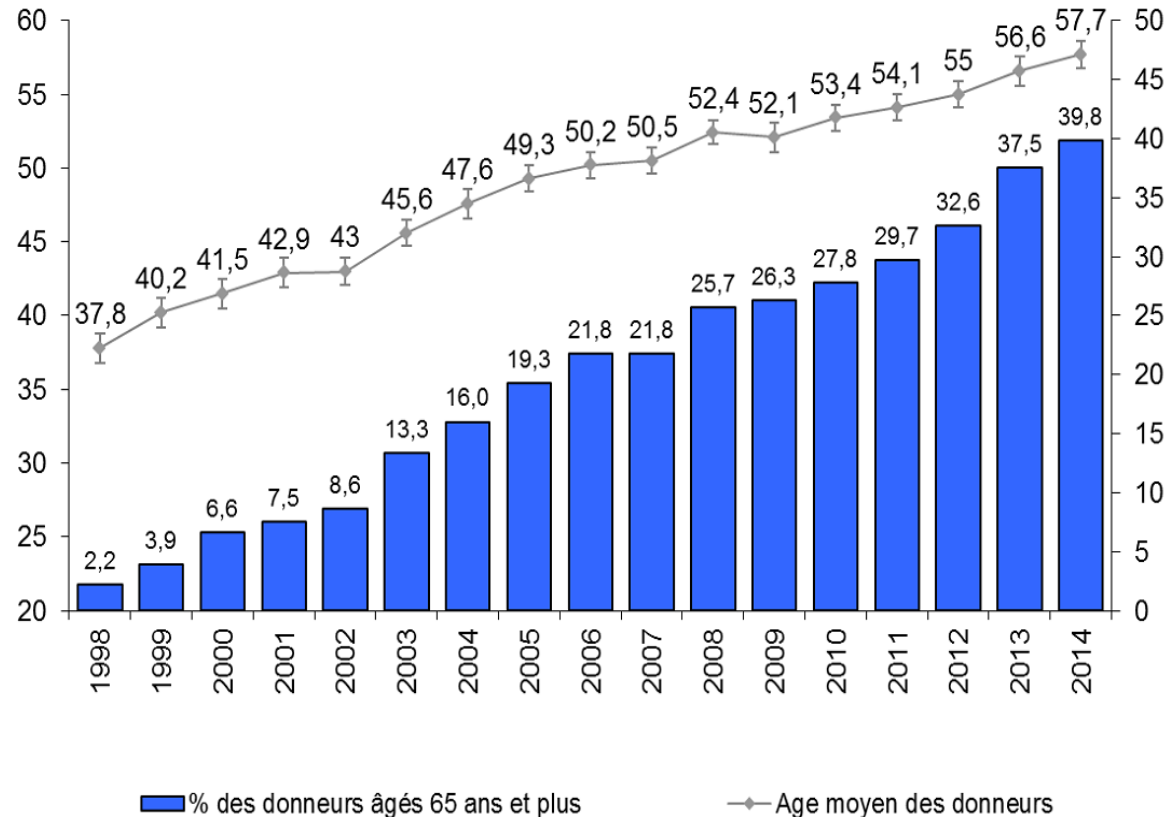


		Incidence cumulée des greffes avec prise en compte du risque concurrent de décès en attente ou sorties pour aggravation en % [IC à 95%]				
Dernière priorité	N	à 3 mois	à 6 mois	à 12 mois	à 24 mois	à 36 mois
Aucune	1580	29 [27-32]	44 [41-46]	57 [54-59]	66 [64-69]	70 [67-73]
SU1	1051	75 [72-78]	81 [78-83]	86 [83-88]	89 [87-91]	90 [88-91]
SU2	205	39 [32-45]	58 [51-64]	74 [67-80]	89 [83-93]	93 [88-96]
Urgence et dérogation	272	24 [19-29]	36 [30-42]	50 [43-56]	60 [53-66]	65 [58-71]

Survival according to urgency status

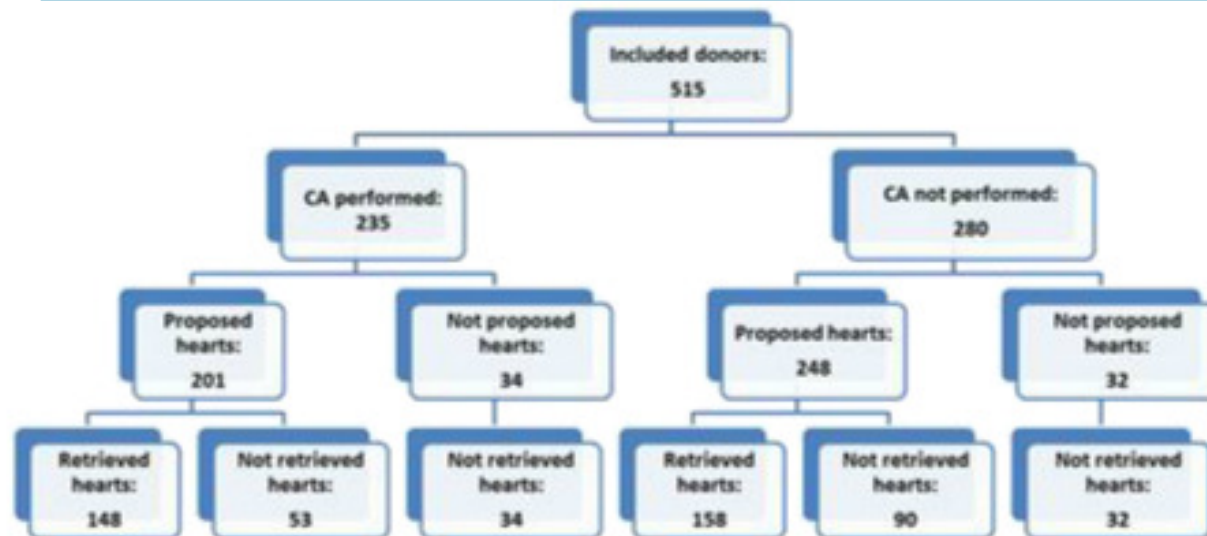


Increasing mean age of utilized donors

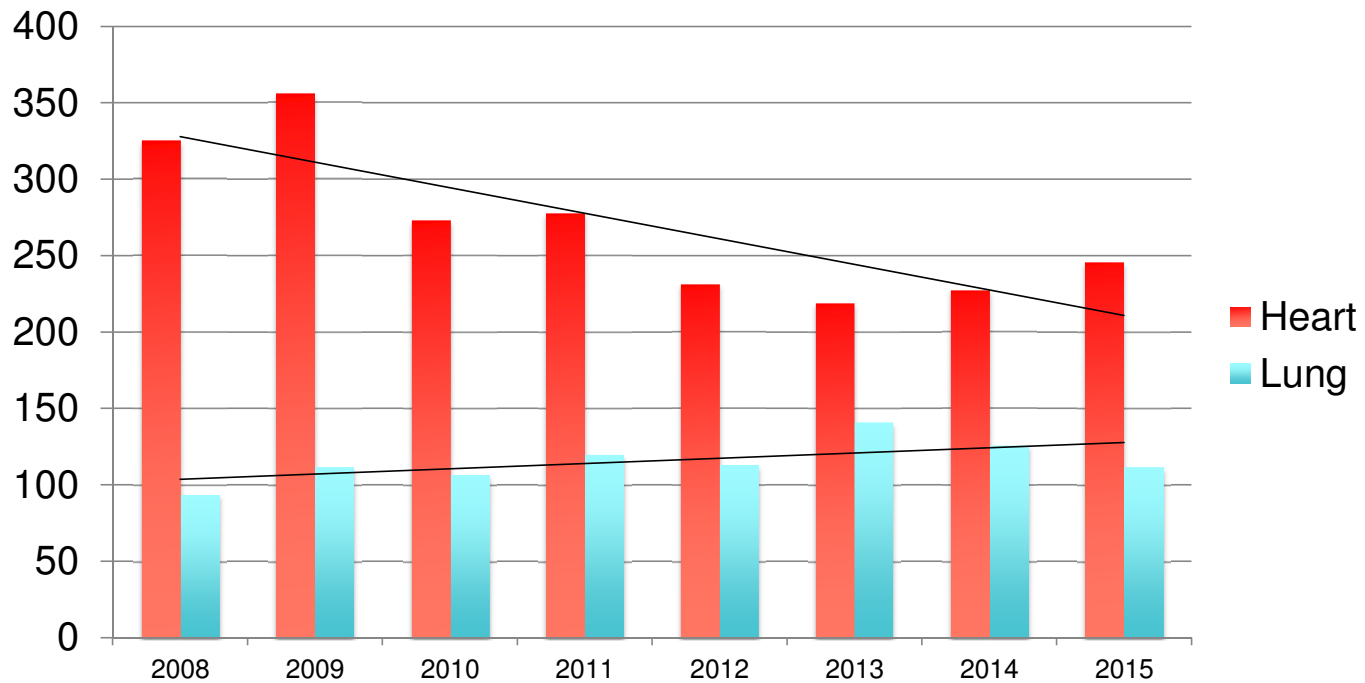


Coronary angiography increases heart utilization

In the CA performed group 74% of organs have been accepted vs. 64% in the CA not performed group (P=0.02)



Heart and Lung Transplant in Italy



Data from the National Transplant Center

Allocation system in Italy

- Standard allocation
 - Based on regional donor pool
- High urgency tier
 - Country-wide organ sharing area
 - ECMO or complicated VAD or IABP plus ventilator
 - Payback for urgency

High urgency for lung transplant

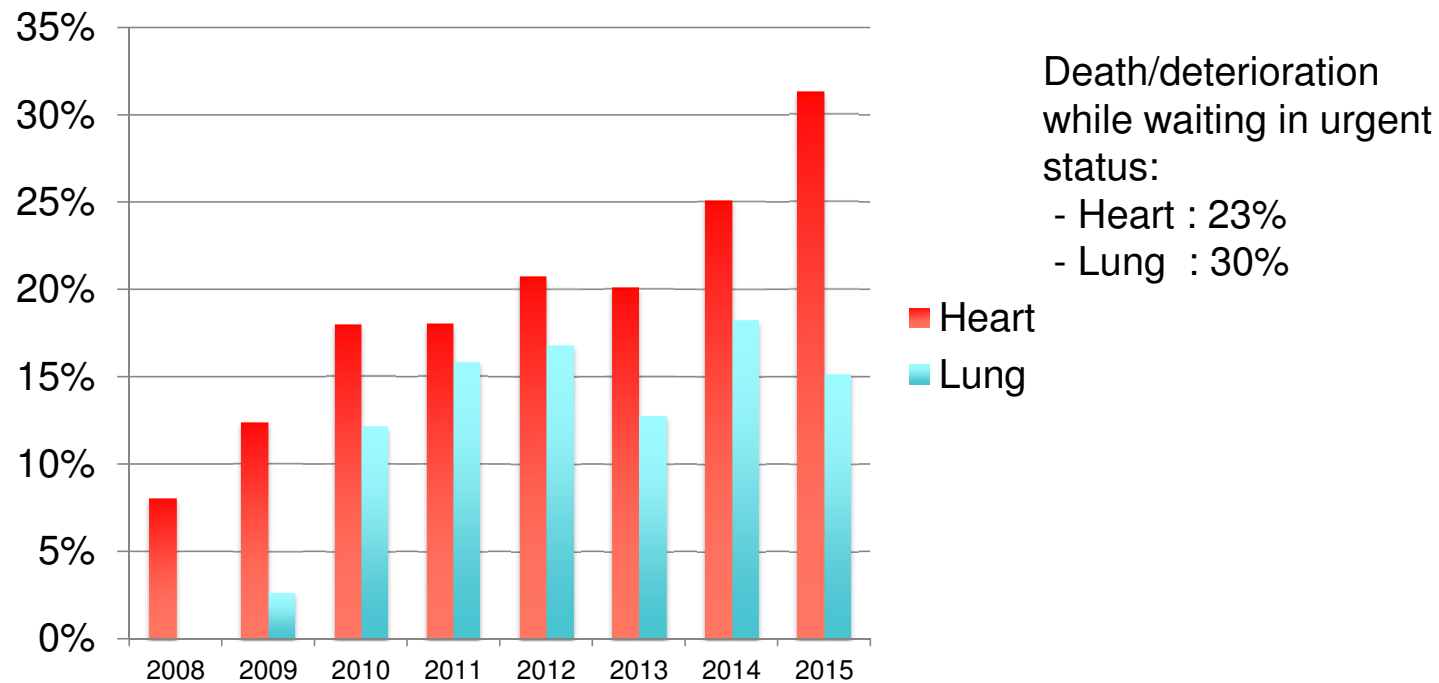
Table 1: Inclusion and exclusion criteria for Italian Urgent Lung Transplantation programme

Inclusion criteria	Exclusion criteria
Age ≤ 50 y/o	BMI < 18 or >30
MV and/or ECLS (except for DECAP®)	Sepsis
Previous LTx waiting list	Multiorgan failure
	Haemorrhagic shock
	Neurological damage
	ECLS and/or MV >14 days

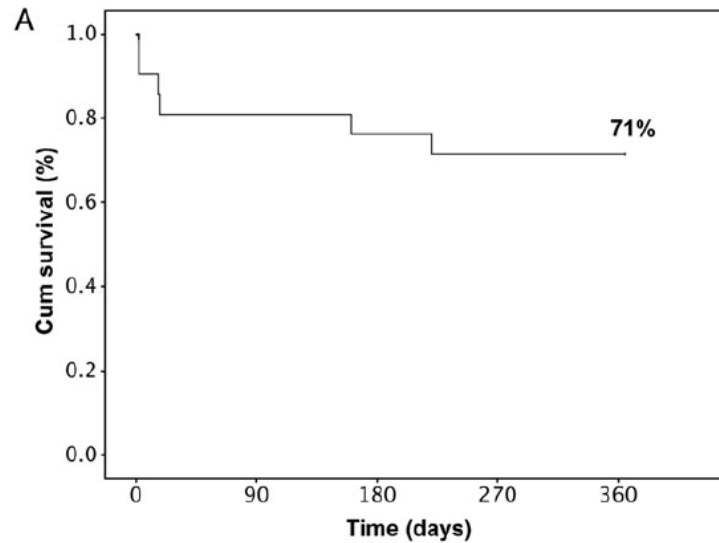
MV: mechanical ventilation, ECLS: extracorporeal lung support, BMI: body mass index; LTx: lung transplantation.

Boffini et al. Interactive CardioVascular and Thoracic Surgery 19 (2014) 795–800

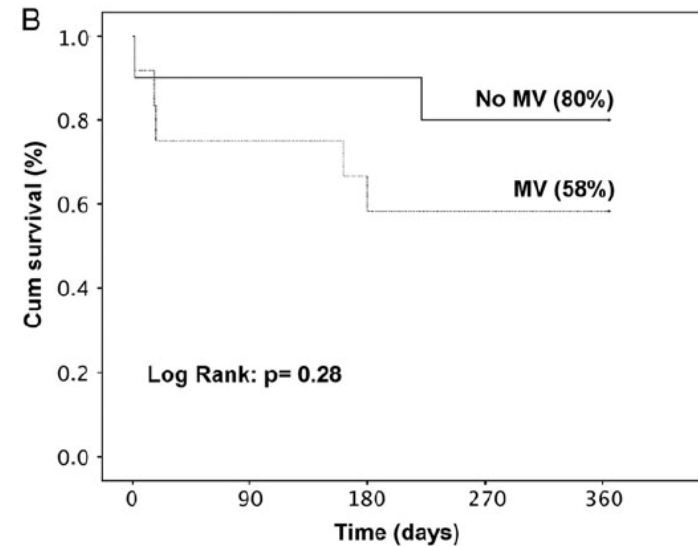
Urgency program in Italy



High urgency lung Tx outcomes



Pts at risk	22	17	16	15	15
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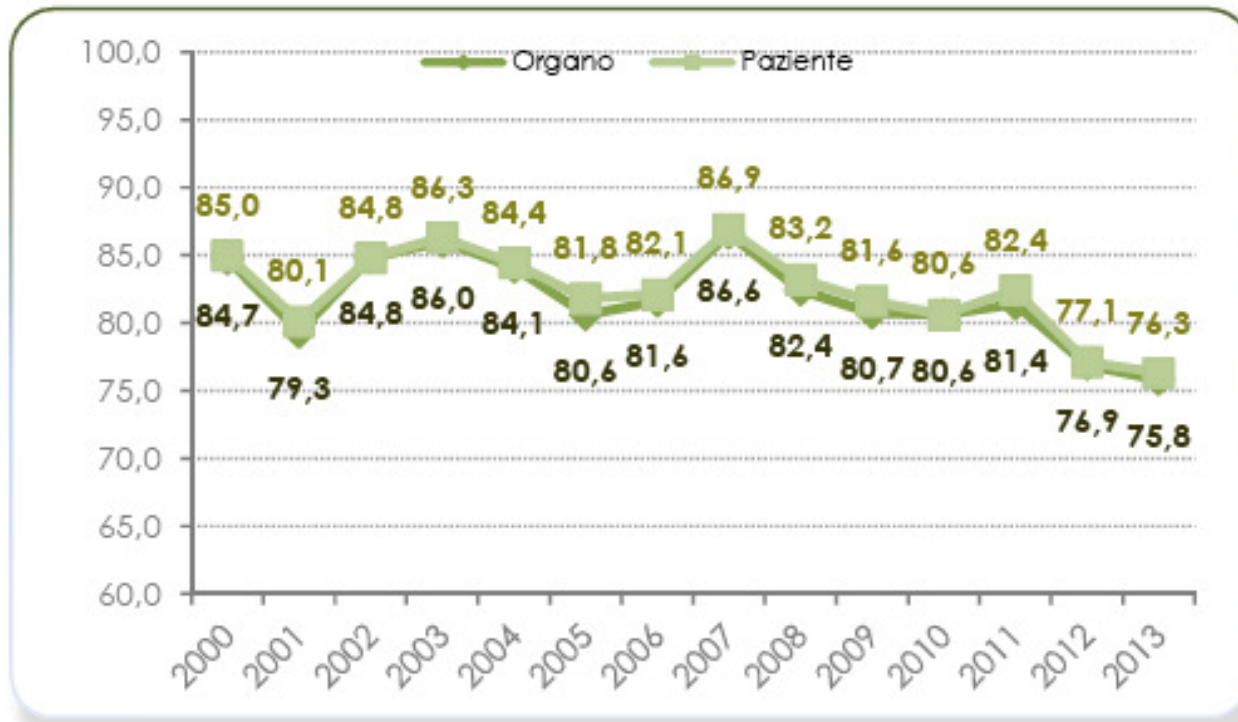


No MV	10	9	9	8	8
MV	12	8	7	7	7

1-y survival for non-high urgency cases: 70%

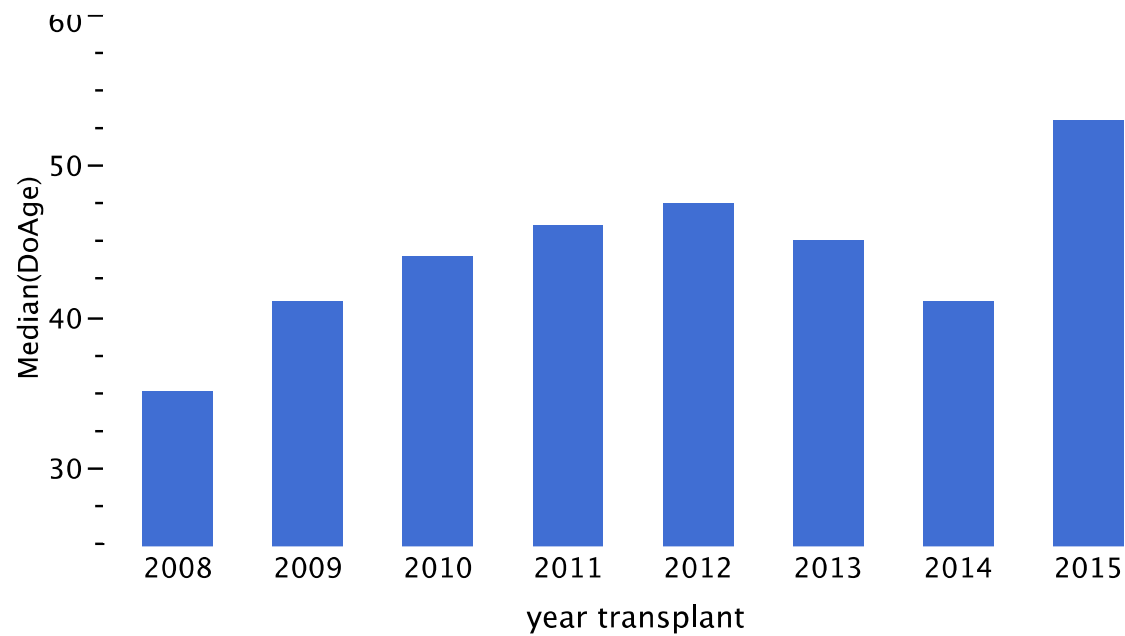
Boffini et al. Interactive CardioVascular and Thoracic Surgery 19 (2014) 795–800

1-y heart survival trend

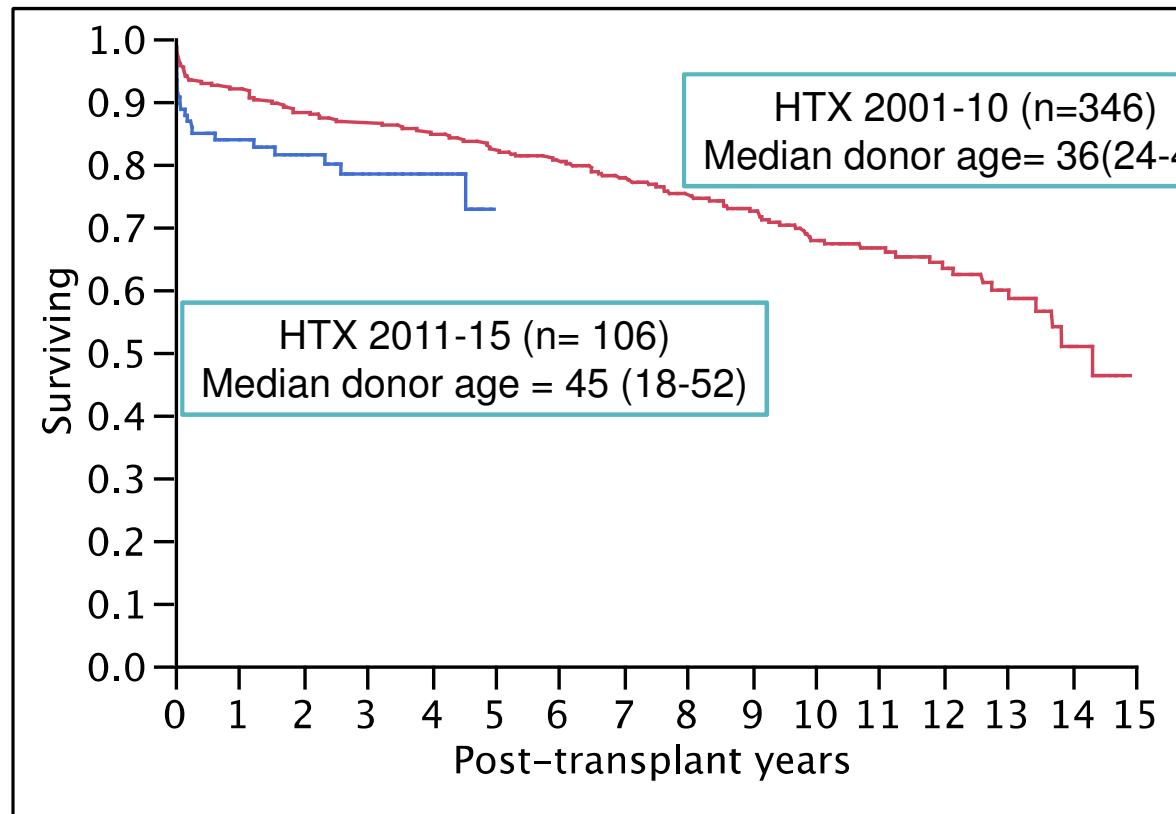


Data from the National Transplant Center

Heart donor age in Bologna



Post-HT survival and donor age in Bologna



Ethical pillars of decision making

- Beneficence

Provide a benefit with transplant

- Non maleficence

Do not run unacceptable risks

- Autonomy

- give the patient the possibility to make an informed and rationale choice

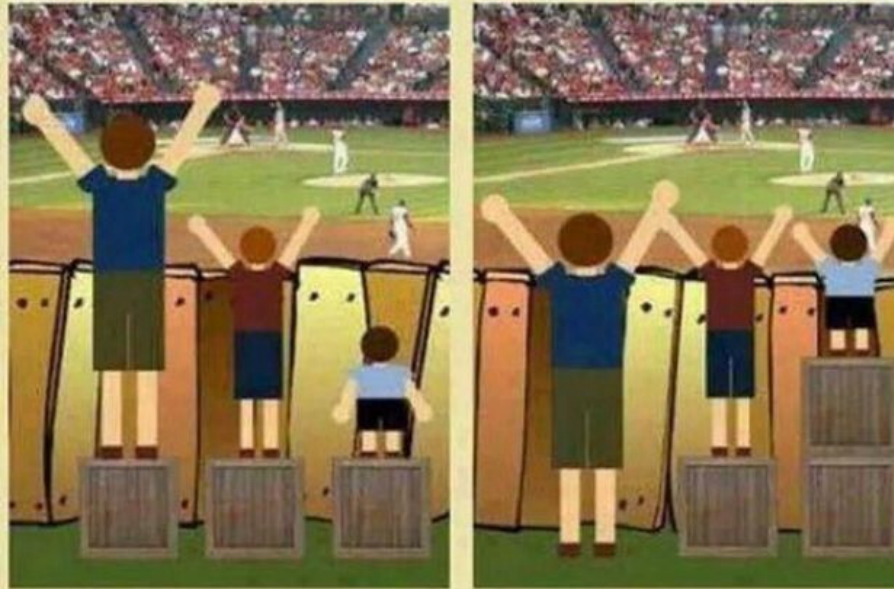
Are we enough rationale and informed to make a choice?

- Distributive justice

- Allocate appropriately a scarce resource

What are the parameters for justice?

Equality doesn't mean Justice



Equality

Justice

Ideal allocation system

- High-priority patients do have a high risk without transplantation;
- Transplantation will be performed with appropriately short waiting times for the highest priority patients
- A reasonable proportion of patients can undergo transplantation at a lower priority level.

No priority system can be effective or even evaluable except in the context of a waiting list length that is matched to the current donor heart supply.

Stevenson LW, J Heart Lung Transplant 2013; 32: 861

Urgency tiers and waiting times in Europe

	Urgency tiers	Transplant rate per tier (%)	Median waiting list (days)
UK	Urgent	60	14
	Non Urgent	40	293
France	SU1	39	9
	SU2	8	102
	Regional urgency	9	219
	Non urgent	45	189
Spain	Urgent 0	14	8
	Urgent 1	21	7
	Non Urgent	66	80
Italy	Urgent	14	3
	Non Urgent	86	292

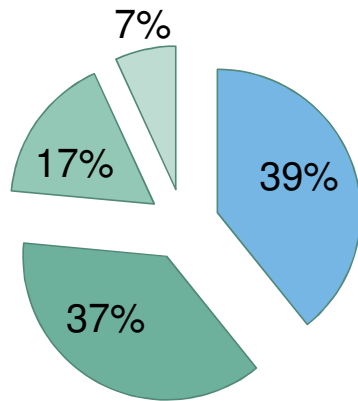
Stehlik J et al J Heart Lung Transplant 2014; 33:977

Distributive justice: set the line to connect competing interests

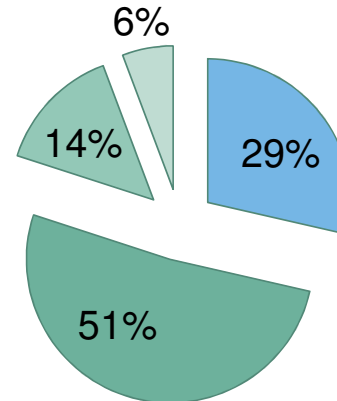
- Urgency allocation algorithms
 - Need to allocate a scarce resource to individuals at greater need
 - Need to allocate a scarce resource to individuals most likely to get a benefit
 - Need to avoid inequalities in the access to transplant of those who would not meet urgency criteria

Blood group disparities

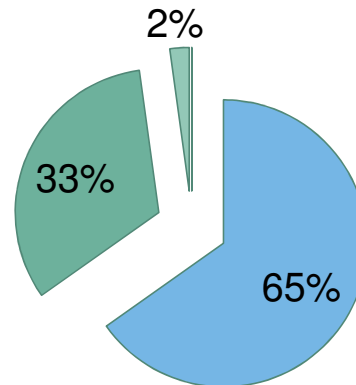
Italian blood group distribution



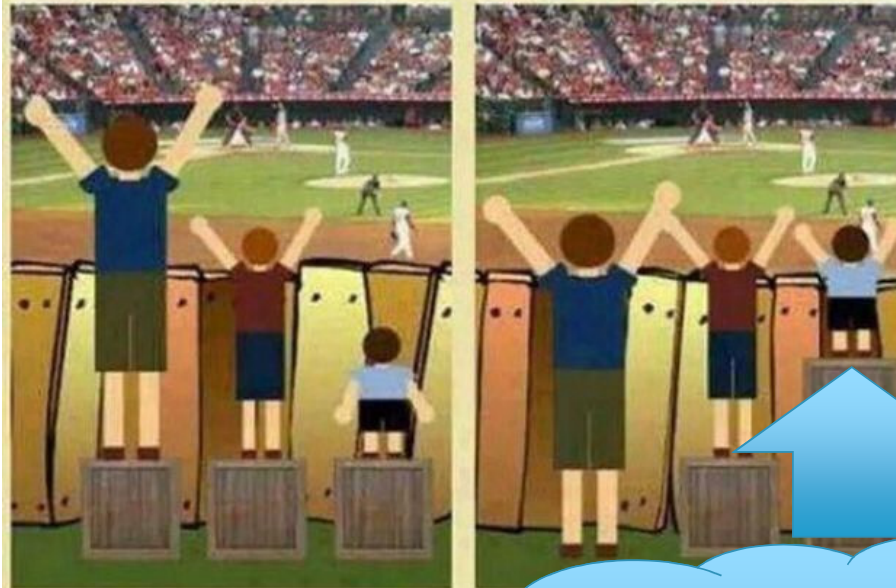
2014-15 HTX blood groups distribution



Current waitlist blood groups distribution



Equality doesn't mean Justice

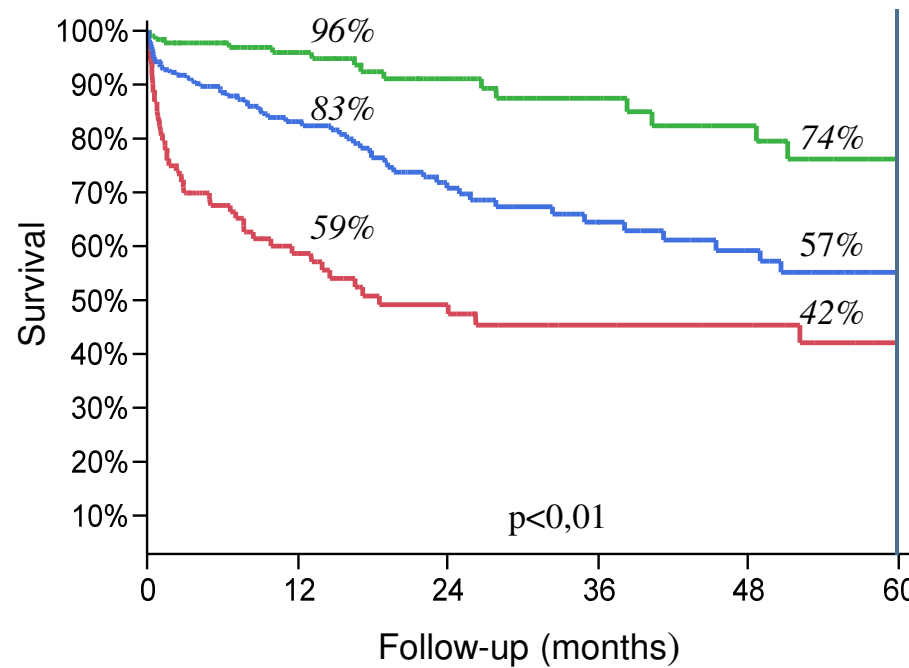


Equality

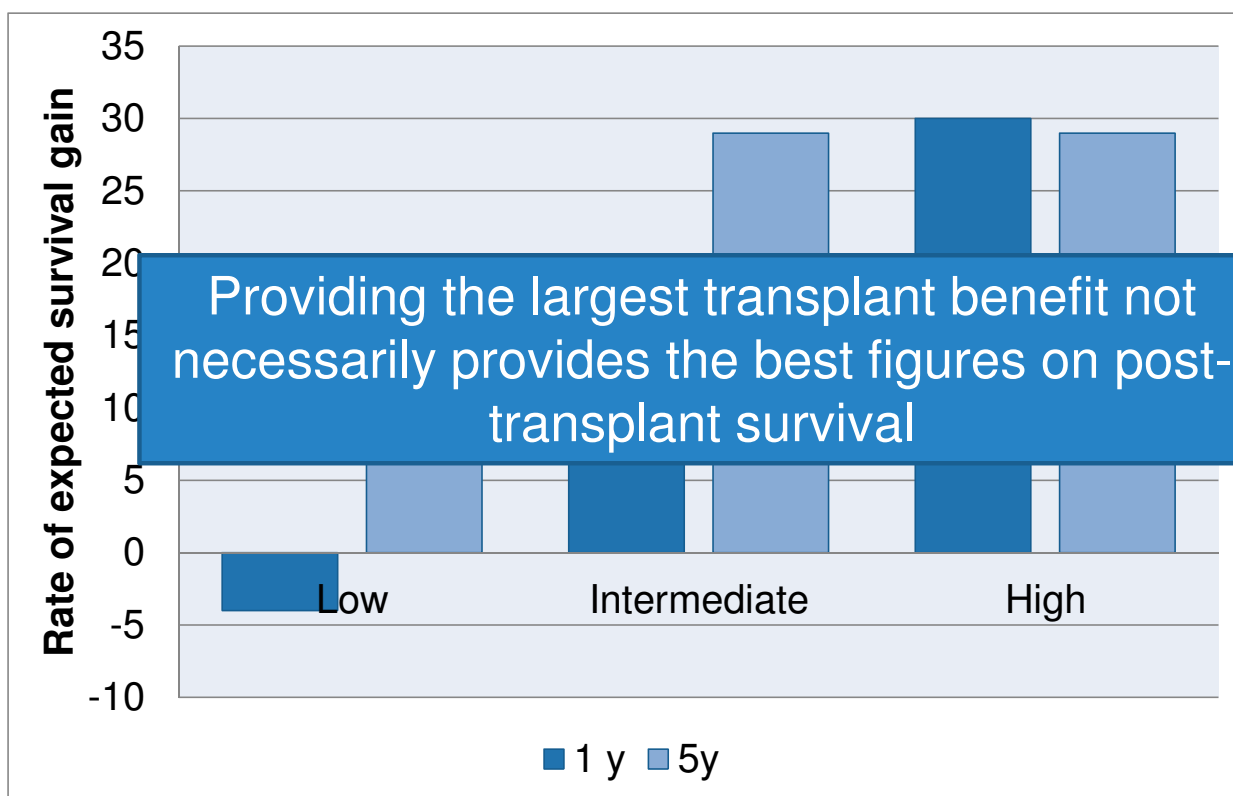
And if this little boy were blind?

Survival in HF patients evaluated for transplant (n=500)

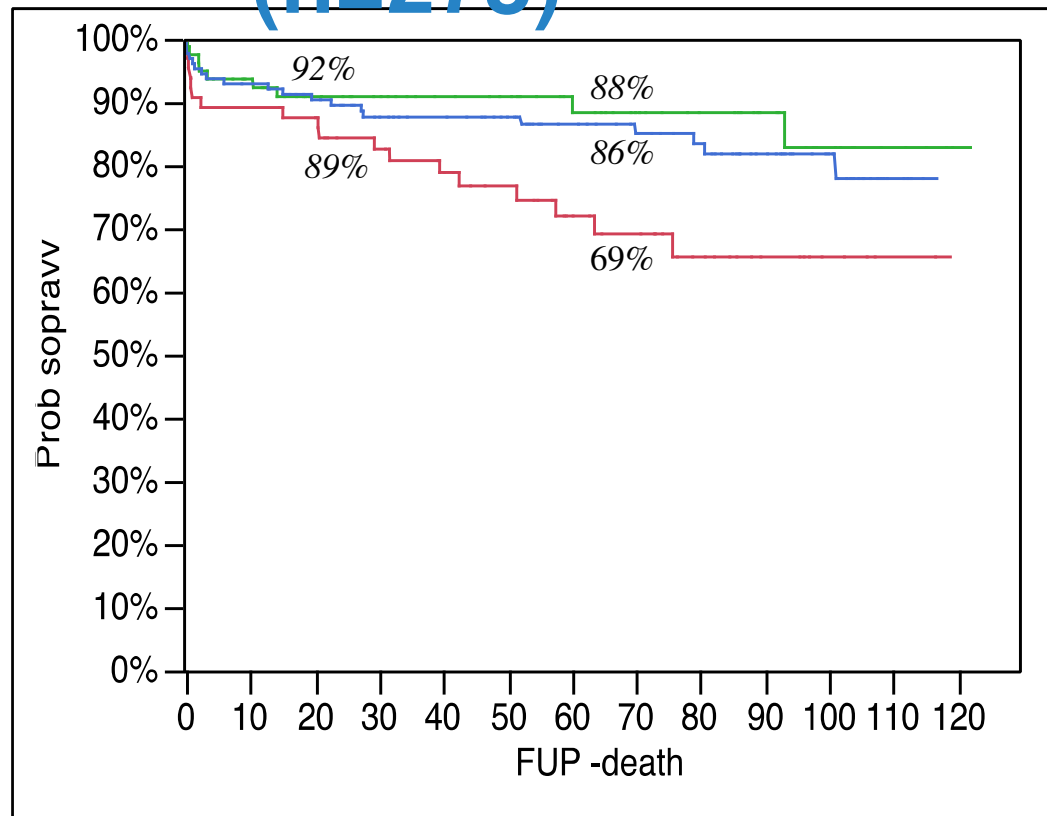
- 7 – 9 Low risk
- 10 – 11 Moderate risk
- > 12 High risk



Transplant Benefit at 1 and 5 years

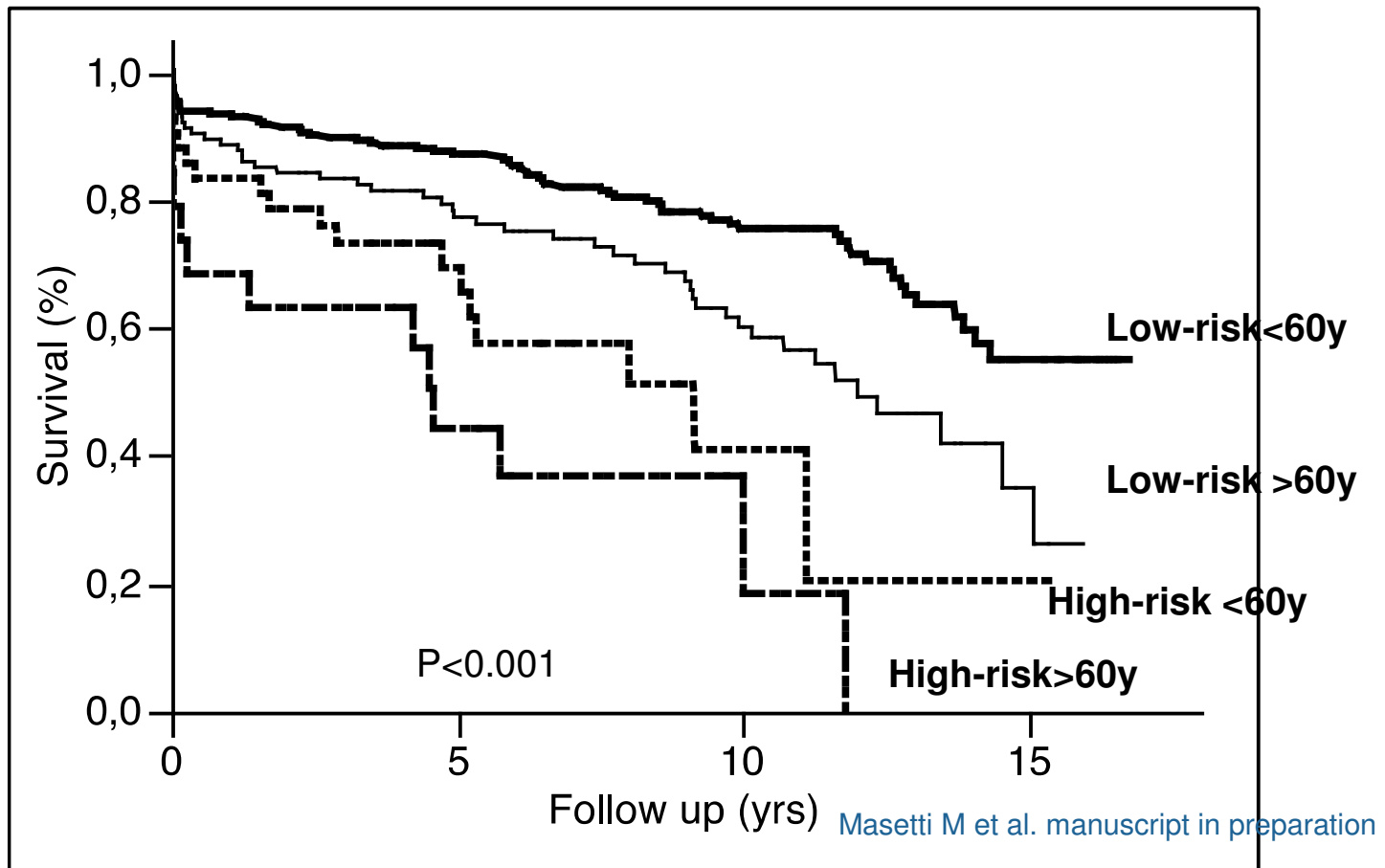


Survival after HT (n=275)



- Low risk
- Moderate risk
- High risk

Age-stratified comorbidity risk



Frailty and post HT survival

TABLE 4.

Outcomes after heart transplantation stratified by frailty

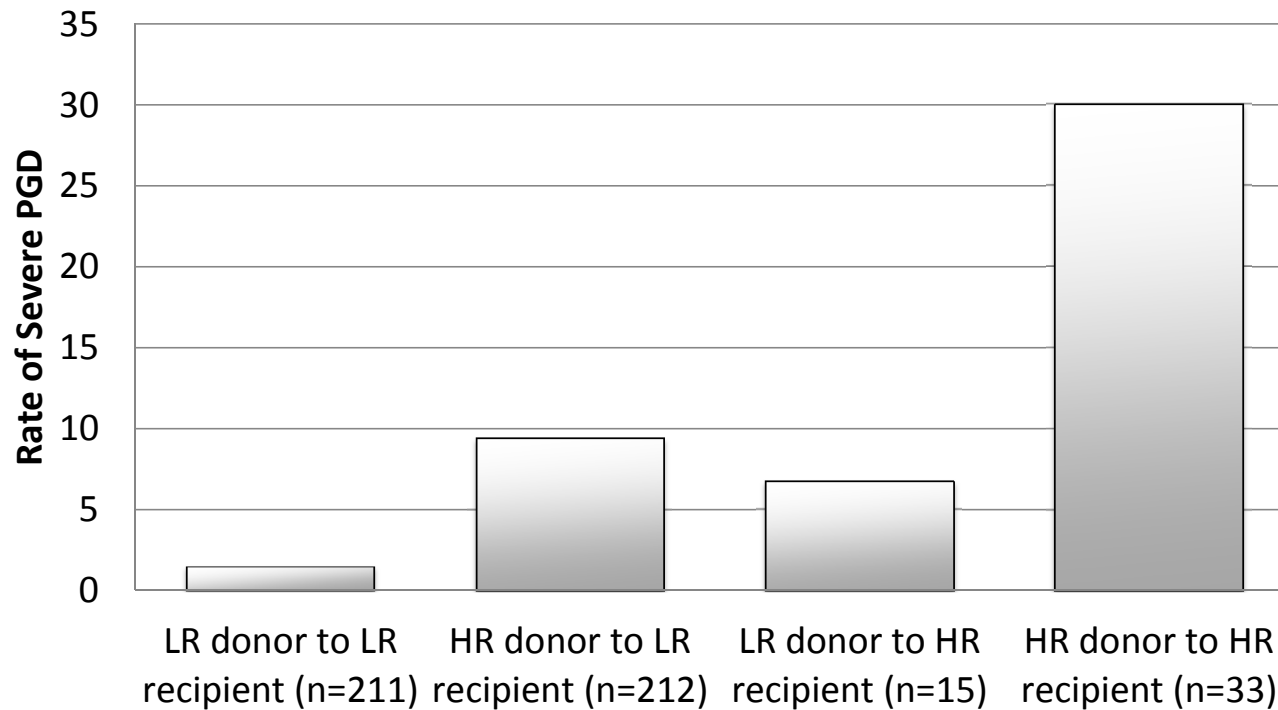
	Total	Nonfrail or prefrail	Frail
	(n =34)	(n = 25)	(n = 9)
Age, y	49 ± 15	50 + 14	46 ± 18
Sex (male:female)	18:16	16:9	2:7
Intubation, h	28 (103)	27 (98)	110 (116)
ICU after HTx, d	7 (5)	6 (4)	8 (10)
LOS after HTx, d	25 (17)	24 (14)	27 (36)
Survival at 6 mo	93 ± 5%	100%	79 ± 14%
Survival at 12 mo	86 ± 8%	100%	52 ± 23%

Values are mean ± SD for normally distributed continuous data, median (interquartile range) for non-normally distributed continuous data, and number for categorical data.

HTx indicates heart transplantation; LOS, length of stay.

Jha SR et al. Transplantation 2016;100: 429–436

Donor-recipient match and outcome



Sabatino M et al. manuscript in preparation

Summary

- Thoracic transplantation numbers are stable overall in Europe, with some emerging countries increasing volume and remarkable loss of volume in some other countries
- Allocation policies are highly variable, but mainly based on a mixed model in which geography prevails on severity (limited number of severity tiers)

Unmet needs

- Shared policies to improve thoracic organ retrieval
- Develop tools to aid clinicians to optimize decision making about appropriate risk matching
 - Balancing the risk of waiting vs. accepting borderline donors (appropriate MCS development)
 - Identify tools to objectively allocate priorities (based on physiology and not on treatment)
 - Auditing systems that set up quality standards with outcome measures accounting for cases complexity, and urgency appropriateness

Question 1

How many urgency tiers are acceptable?

A. 1

B. 2

C. 3

D. more

Question 2

Should the donor risk be considered in the allocation algorithm?

- A. Yes
- B. No

Question 3

Should the recipient risk enter the allocation algorithm?

A. Yes

B. No