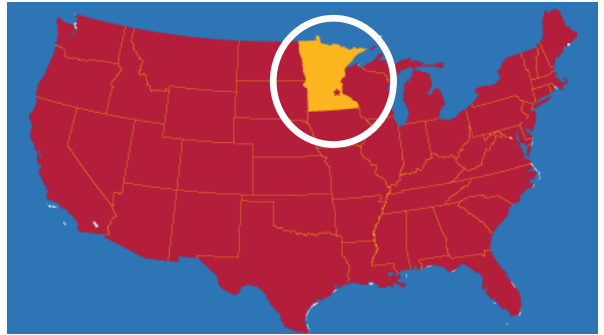


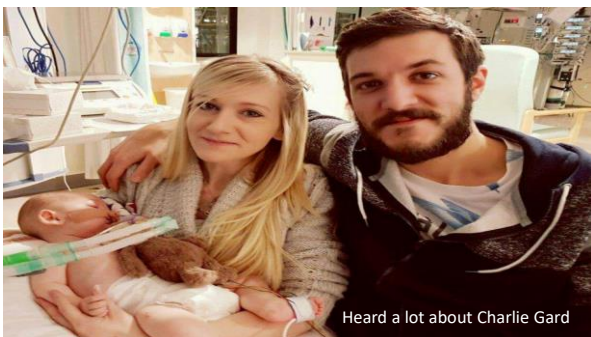
# Rationing Organs: U.S. Approach

Oxford Uehiro Centre for Practical Ethics  
June 20, 2018

Thaddeus Mason Pope, JD, PhD



Thank you

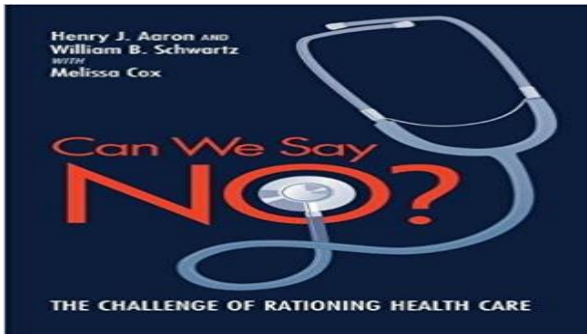


Heard a lot about Charlie Gard

“Take him  
to the **U.S.**”

# Why?

“They’ll try  
**anything.**”



# Roadmap

4

Scarcity

Structure

Principles

By which organs are allocated

Process

3

Livers

Lungs

Kidneys

Scarcity

722,000  
transplants  
(1988 – 2018)

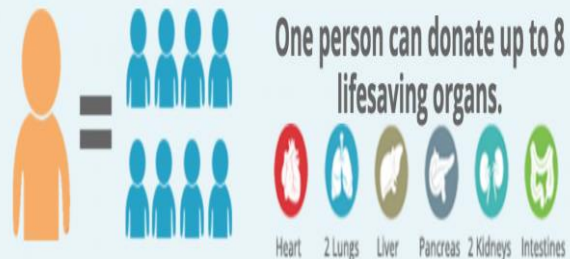
2017

MORE THAN  
**10,000**  
*2017—record breaking year*



10,000 donors  
35,000 transplants

One person can donate up to 8 lifesaving organs.



Heart 2 Lungs Liver Pancreas 2 Kidneys Intestines



Supply <  
Demand

Supply

35,000 transplants

---

29,000 Deceased

6000 Living



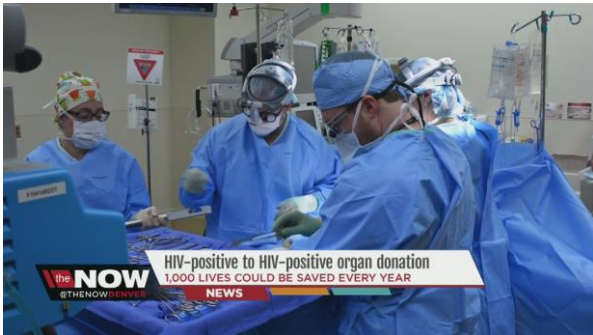
**Living**  
donors  
usually  
“directed”  
to **family**

Focus on 29,000  
annual **deceased**  
donor transplants

**Where** do we get  
deceased donor  
organs?

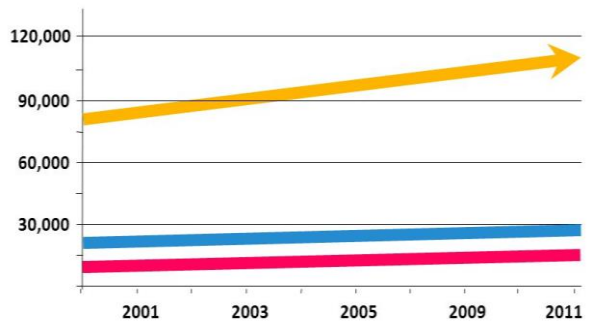
# Opt-in

Innovating ways to increase **supply**



- Opt-out
- Market
- Devices
- Xenotransplantation
- Stem cell (esp. embryonic)
- Expand definition "death"
- Transplant tourism

Supply is **flat**



# Up



# Down

## Usually after brain death

### VIEWPOINT

## The 50-Year Legacy of the Harvard Report on Brain Death

**Robert D. Truog, MD, MA**  
Center for Bioethics,  
Department of  
Anesthesiology, Critical  
Care, and Pain  
Medicine, Boston  
Children's Hospital,  
Harvard Medical  
School, Boston,  
Massachusetts.

**On August 5, 1968**, an ad hoc committee at Harvard Medical School published a landmark report that laid the groundwork for a new definition of death, based on neurological criteria.<sup>1</sup> The authors, under the leadership of anesthesiologist Henry Beecher, stated that their primary purpose was to “define irreversible coma as a new criterion for death.” The concept of brain death has guided clinical practice for 50 years even though vigorous debate about its legitimacy has never ceased.

Beecher’s committee produced criteria. Coma could be considered irreversible if, over a 24-hour period, the patient responded to stimuli, had no spontaneous breathing, and had no reflexes; a flatogram provided valuable confirmation of brain function. These criteria clarified for which clinicians could withdraw life support. The criteria also facilitated organ transplantation by declaring the donor dead prior to ventilator and cardiac arrest. This permit withdrawal of organs in an optimal condition while legal responsibility from the clinicians is transferred to the recipient.

**Thaddeus Mason Pope, JD, PhD**  
Mitchell Hamline  
School of Law, St. Paul,

### The Committee, Its Contexts, and Its Recommendations

The development of positive pressure ventilators in the

# Under attack



# Demand

# 115,000

| Organ             | Candidates |
|-------------------|------------|
| Kidney            | 95,188     |
| Liver             | 13,962     |
| Pancreas          | 891        |
| Kidney / Pancreas | 1,667      |
| Heart             | 4,022      |
| Lung              | 1,450      |

| Organ             | Candidates | Transplants |
|-------------------|------------|-------------|
| Kidney            | 95,188     | 19,849      |
| Liver             | 13,962     | 8,082       |
| Pancreas          | 891        | 213         |
| Kidney / Pancreas | 1,667      | 789         |
| Heart             | 4,022      | 3,244       |
| Lung              | 1,450      | 2,449       |

## Average Median Wait Time

Kidney 5 years  
 Liver 11 months  
 Heart 4 months  
 Lung 4 months

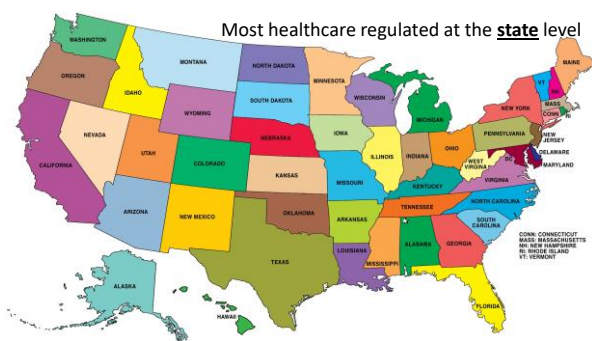
**20 die every day**  
 from lack of organs



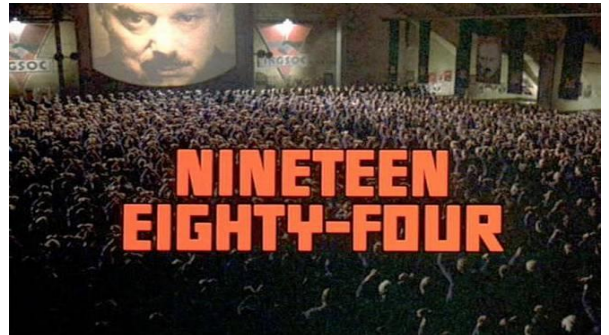
That's **scarcity**  
of deceased  
donor organs

**How** are they  
allocated?

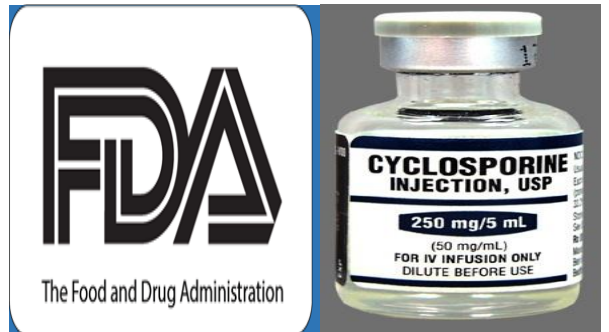
**Structure**



# 1984



# 1983



immunosuppressant  
decreased morbidity  
& enabled **routine**  
transplantation

# 1984

“national resource”

“public good”

National Organ  
Transplant Act

“**streamline** the  
organ distribution  
process”

Organ Procurement  
& Transplantation  
Network (OPTN)

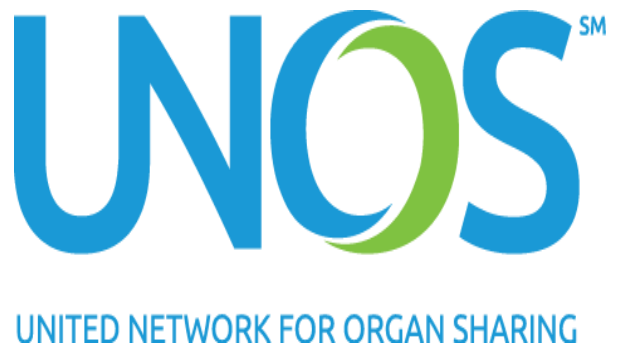
**2** Key  
roles

(1) Maintain **names**  
of individuals who  
need transplants

(2) When organs become available, **match** organs with appropriate patients



USGOV **contracts** with private non-profit to run OPTN

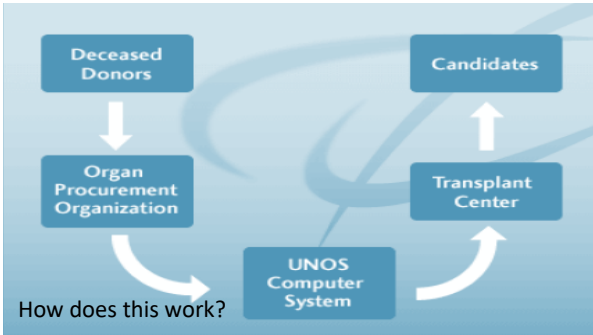
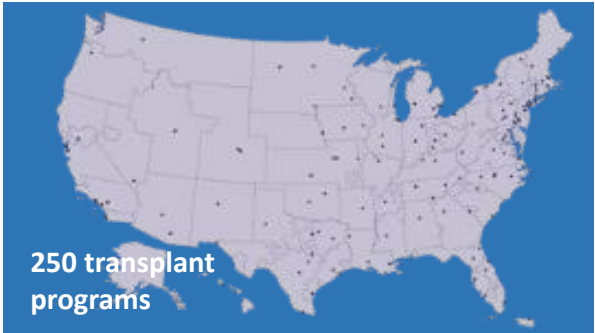
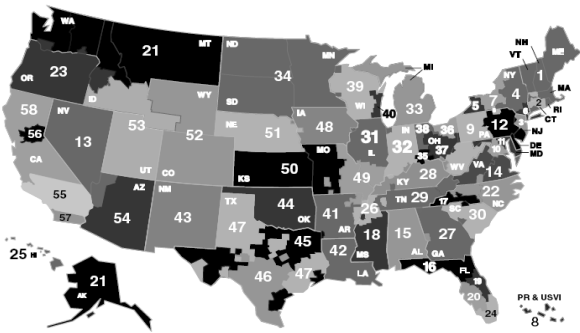


**UNOS** does the rationing

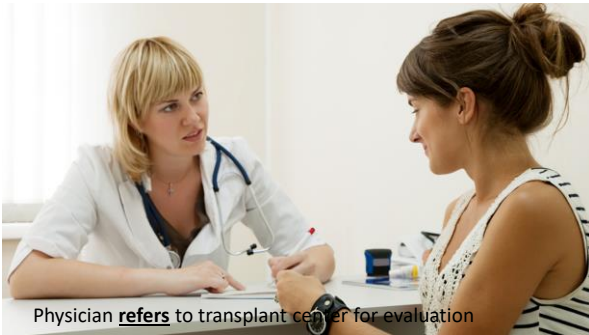
We will focus on **UNOS**

“network”

2 Other players



Candidate



Medical condition  
Family support  
Financial situation

\$600,000  
+ \$7000/mo.

Many lack **access**  
to waiting list  
But we'll focus on  
the **list itself**

Good candidate  TC add  
to "list"



Non-U.S. = **1%**  
organ wait list

Turn from the candidate to the

**Donor**

Hospitals **must**  
**notify** local OPO  
of potential organs

OPO will obtain  
**consent** for donation  
once donor BD

OPO gathers **information**  
**about donor** and enters  
data into UNOS program

organ size and condition, blood type, and tissue type



# Matching

UNOS computer system **ranks** candidates based on the allocation policy for that organ

**Ranked list**

| OPO  | Donor ID | Organ | Match ID | Allocation Status | Provisional Acceptance | Refusal | Acceptance | Match Item          | Date and Time       | Initial Notification Date & Time |
|------|----------|-------|----------|-------------------|------------------------|---------|------------|---------------------|---------------------|----------------------------------|
| CAOP | 170330   | SP    | 660316   | In Progress       | 0                      | 1       | 0          | 3502011 12:42:00    | 3502011 12:42:00    | 3502011 1:36:02 PM               |
| CAOP | 170330   | IB    | 660316   | In Progress       | 0                      | 1       | 0          | 3502011 12:42:00    | 3502011 12:42:00    | 3502011 1:36:02 PM               |
| UNAC | 170205   | KG    | 660205   | In Progress       | 0                      | 25      | 0          | 3502011 10:44:48 AM | 3502011 10:44:48 AM | 3502011 4:28:11 AM               |

UNOS or OPO **contacts** transplant centers with patients on the computer-generated ranked list.

What determines

# Ranking

on the list

# Principles



Allocation policies  
must satisfy

**2** principles

“achieve the **best use**  
of donated organs”

Utility

Efficiency

“promote **patient access**  
to transplantation”

Equality

Fairness

**Utility**

~~Maximize **social** benefit~~

~~Give to those who will do  
most "good"~~



They Decide Who Lives, Who Dies:  
Medical Miracle Puts Moral Burden on Small Committee

TIME November 9, 1967

Medical  
benefit

Key measure

Maximize  
**life-years** gained

But utility is **not**  
the only allocation  
principle

Justice

Minimize **disparities**  
in opportunity among  
similarly situated  
candidates

Justice & Utility  
often **conflict**

| Justice               | Utility                    |
|-----------------------|----------------------------|
| Most urgently in need | Less likely to live longer |

| Justice         | Utility               |
|-----------------|-----------------------|
| Waiting longest | Will not benefit most |

| Utility        | Justice        |
|----------------|----------------|
| Maximize QALYs | Disfavor older |

UNOS must honor **both** principles

UNOS does **not** allocate organs to produce maximum medical good

UNOS is concerned not only with **amount** of medical good

But also with how the good is **distributed**

# Process



# 3 organs

Livers  
Lungs  
Kidneys

# Livers

Candidates 14,000  
Transplants 8000

## Before 2002

# wait time

Liver went to  
patient **added**  
to list **first**

Justice  
Utility

After  
2002

Need

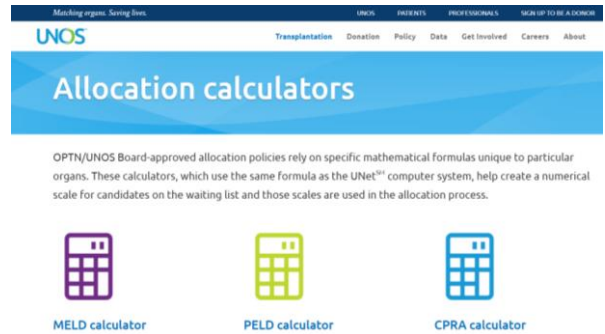
Still  
Justice  
Utility

Now a different  
notion of justice

Model for End-Stage  
Liver Disease (MELD)

# Score

**how urgently** patient  
needs liver transplant  
**in next 3 months**



Matching organs. Saving lives.

UNOS PATIENTS PROFESSIONALS MEAN UP TO BE A DONOR

Transplantation Donation Policy Data Get Involved Careers About

## Allocation calculators

OPTN/UNOS Board-approved allocation policies rely on specific mathematical formulas unique to particular organs. These calculators, which use the same formula as the UNet™ computer system, help create a numerical scale for candidates on the waiting list and those scales are used in the allocation process.

MELD calculator PELD calculator CPRA calculator

6 → 40  
Less ill Gravelly ill

35 ICU  
25 Still at home

**Highest** MELD  
gets the liver

**Main factor**  
Short term  
mortality risk



66yo MELD 35

**before**

22yo MELD 25

# BUT

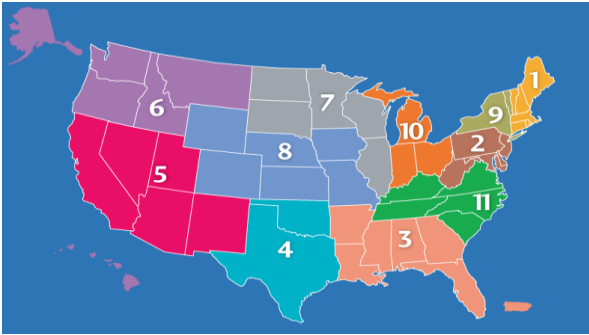
22yo MELD 25 likely  
to **live longer** with  
liver – more QALYs

| Justice                     | Utility                          |
|-----------------------------|----------------------------------|
| Most<br>urgently<br>in need | Less likely<br>to live<br>longer |

| Justice | Utility |
|---------|---------|
| ↑       | ↓       |



Time for  
Geography

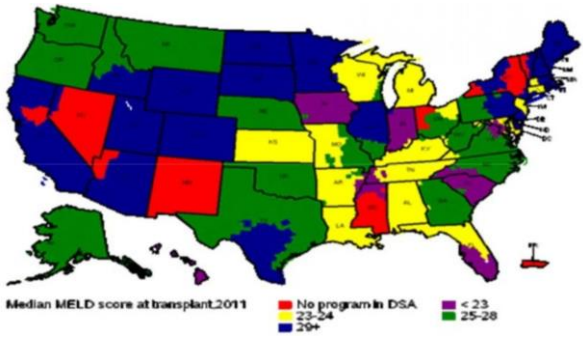


Not 1 list  
58 lists

**Highest** MELD  
gets the liver

Highest MELD  
**in your OPO**  
**service area**

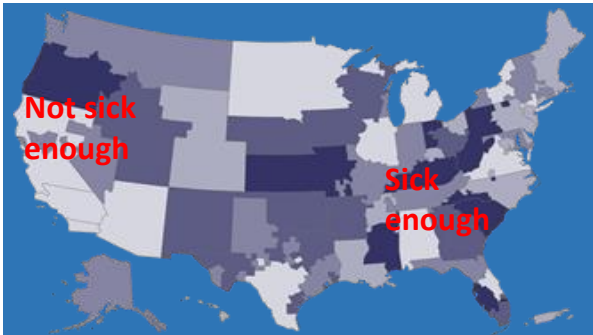
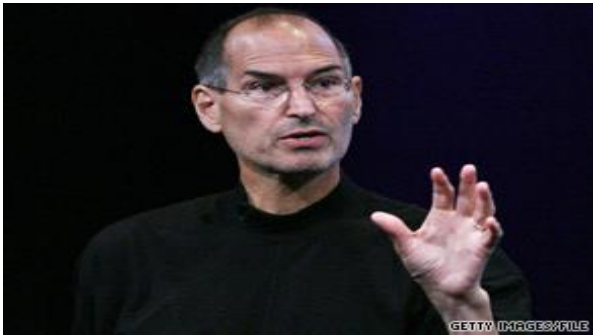
Variability



# Median MELD

Indiana = 20  
Los Angeles = 40

Wait list **varies**  
days to years



## Unhealthiest States in the U.S.

Eight of the 10 unhealthiest states are located in the South:



# Debate on geographical priority

# Utility

reasons for locality

Lower ischemia time

Better organs

More willing to donate

But . . . **not** going to patients who could most benefit

# Justice

reasons for locality

National system

Geography **not** morally  
relevant (treat Miami and  
Memphis same)

# Lungs

Candidates 1450

**Transplants 2450**

Like livers, wait time  
plays limited role

## Goal

Reduce waitlist deaths

Lung allocation score

1 - 100

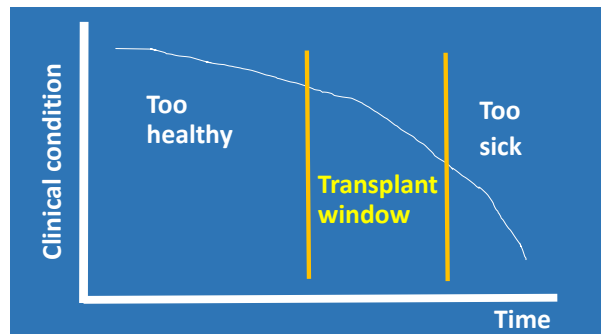
## Most weight

Risk of death w/o  
transplant (urgency)

## Some weight

Probability of post-  
transplant survival (utility)

Must be sick . . .  
But not **too** sick



**Justice**

Urgent  
need  
rank 1st

**Utility**

Too sick  
to benefit  
most

**Utility**

Avoid  
futile TP

**Justice**

Deny sick  
in need

## Covered

Livers

Lungs

# Kidneys

Candidates 95,000

Transplants 20,000

## Before

# 2014

# Waiting time

# Fairness



Utility



No urgency factor  
like livers and lungs

**BUT**

Push for  
**more** utility





**After  
2014**

**More** emphasis  
on utility

Better kidneys



Healthier patients

Every kidney gets Kidney Donor  
Profile Index (KDPI) score

**How long** kidney is likely to  
function compared to other  
kidneys

Each kidney candidate  
gets an individual  
Estimated Post-Transplant  
**Survival** (EPTS) score

**Top 20%** kidneys  
first offered to patients  
likely to last longest

# BUT

**Limit** to utility

**Not** age matching

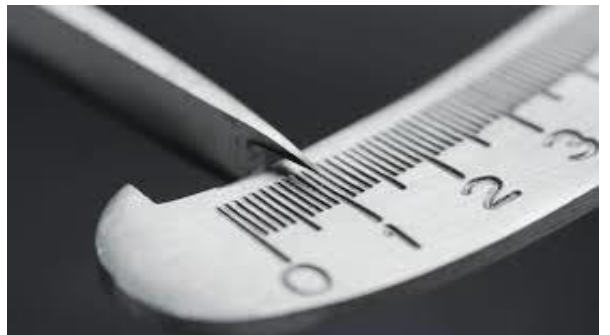
Young → young

Old → old

Remaining 80%

still **wait time**

# Conclusion



**Coming up****Heart allocation changes**

- [Modify adult heart allocation](#)  
*12/2016 Board action*
- [Clarification of adult heart allocation](#)  
*8/2017 Executive Committee action*
- [Review board guidance on HCM and RCM exceptions](#)  
*8/2018 Board action*

**Liver allocation changes**

- [Enhancing liver distribution](#)  
*12/2017 Board action*
- [Establishes a National Liver Review Board](#)  
*6/2017 Board action*

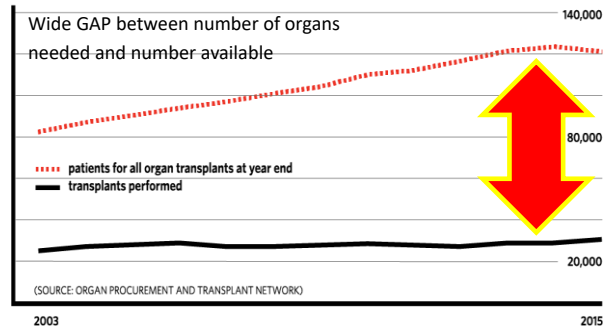
**VCA allocation changes**

- [List covered body parts - 1 of 2](#)  
*6/2016 Board action*
- [List covered body parts - 2 of 2](#) - Effective 9/1/2018  
*6/2016 Board action*

**Update transplant hospital definition***12/2016 Board action***Pending implementation and notice to members**

[Modifications to the distribution of deceased donor lungs](#)  
*6/2018 Board action*

Flux

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