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of BIOETHICS

Recent Headlines in Transplant Ethics

Olivia Kates MD, MA
Johns Hopkins University

Agenda:

- Some basics
- What is allocation out of sequence?
- What is normothermic regional perfusion?
- What's up with xenotransplantation?

Transplant Ethics



ISHLT Statement on Transplant Ethics

CONTRIBUTING AUTHORS

The ISHLT Ethics Committee: Olivia S. Kates, David W. Bearl, John H. Dark, Kavita Dave, Savitri E. Fedson, Edward R. Garrity, Tomoko S. Kato, Cecilia Nucci, Brian Wayda, Barbara J. Wilkey

Introduction

Transplantation is ethically complex, and Ethics Committees composed of panels of experts play a vital role in advancing the field to its fullest potential. The most urgent questions continue to evolve and attract the focus of Ethics Committees seeking to chart an ethically-drive course for the future of transplantation.¹⁻³

The Principles

Respect & Concern for Persons



Donation must be voluntary and free from coercion or exploitation



Pre-mortem clinical care must be separate from organ donation; consider/pursue donation only after death occurs



Prohibition on the sale or exchange of organs

Collective Good & Net Utility



Allocation should be efficient, guided by medical benefit



Only medical or transplant-specific criteria should be used to determine allocation



No social worth/status criteria

Justice



Allocation should also be fair, guided by justice

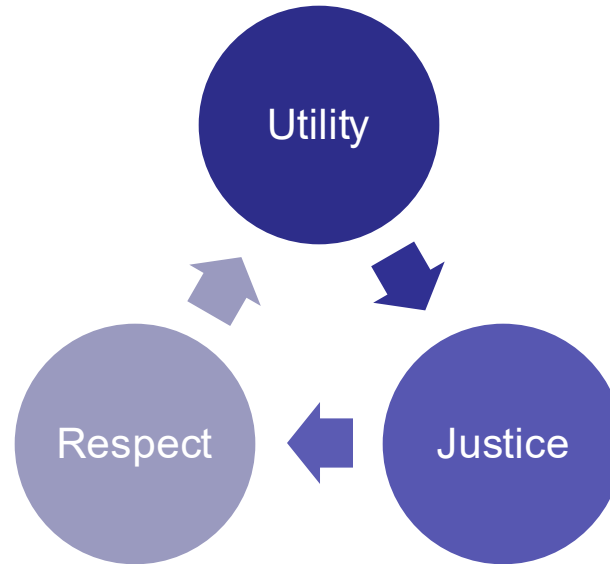


Those who are sickest may and have greatest need may deserve additional consideration

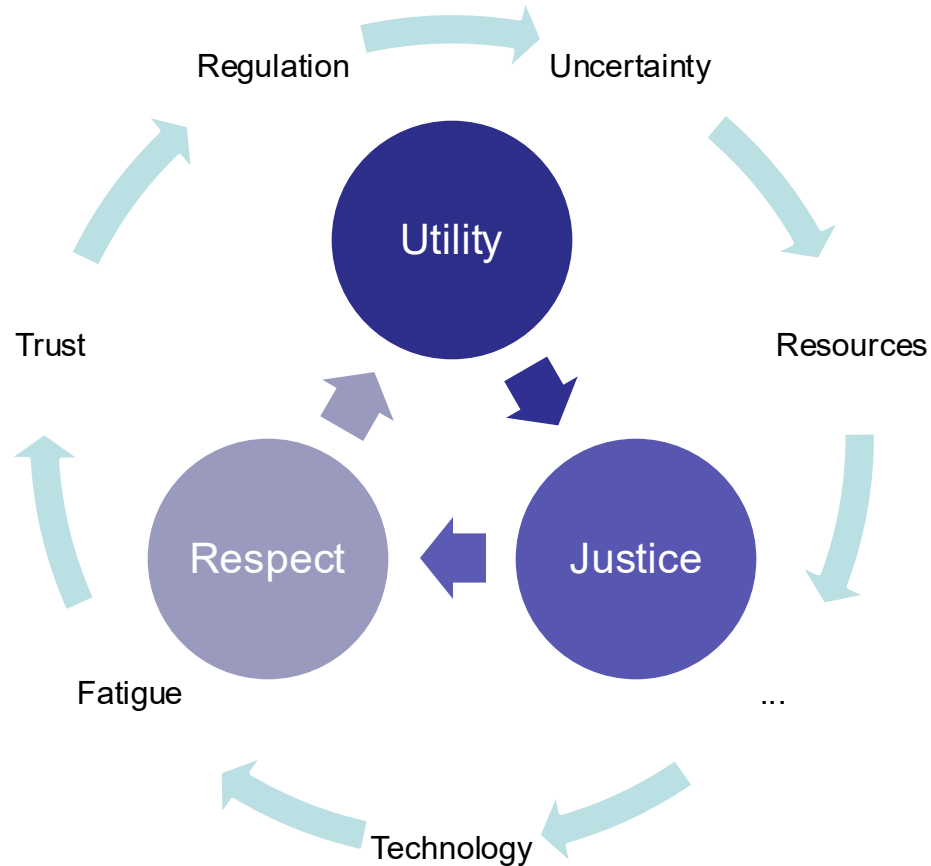


Freedom from discrimination

General Dilemmas



General Dilemmas



General Dilemmas

- To maximize the net utility from transplantation (for example, to save the most years of life), might call for:
 - Actions that infringe on peoples' dignity and autonomy
 - Actions that are unfair
- Transplantation exists in a real world, with limitations:
 - In what is **possible** based resources and technology
 - In what is **known** based on available knowledge
 - In what is **allowed** based on regulation
 - In what is **done** based on human foibles

Allocation Out of Sequence

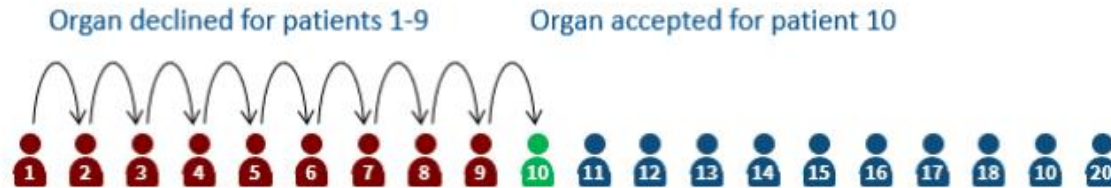
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- Why do it?
- Why is it in the news?
- What are the ethical issues?

Allocation Out of Sequence

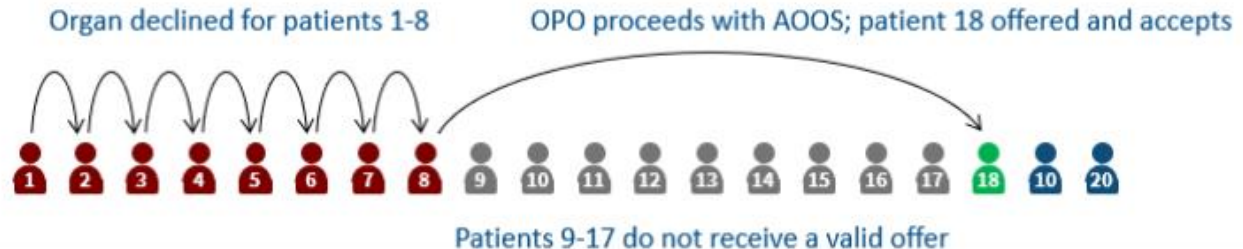
Waitlist contains patients ordered
by OPTN policy-defined sequence



Policy-compliant allocation uses
iterative offers to patients in order



In AOOS, some patients are not
actually offered the organ.

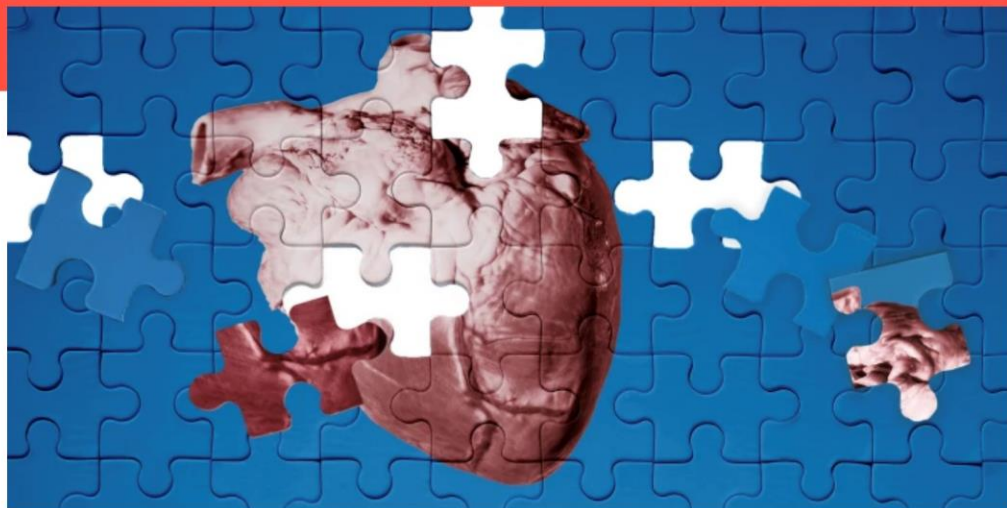


Why?

- 2020: Centers for Medicare and Medicaid Services (CMS) set new requirements for Organ Procurement Organizations (OPOs) based on
 - Number of organs procured
 - Number of organs transplanted

Organ donations get wasted every year. That's killing people like me.

Many of the government contractors responsible for getting organs to transplant recipients are failing on a very basic level.



Poor performance and lack of accountability keep thousands of organs from being recovered properly each year. Adrian Lam / NBC News

May 25, 2020, 10:01 AM EDT

By Tonya Ingram



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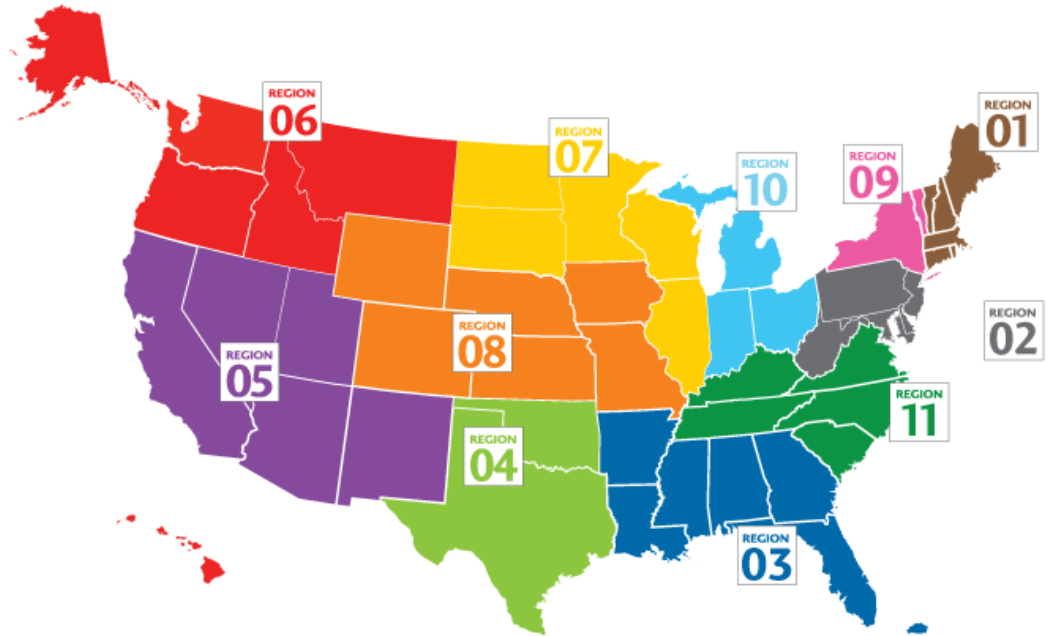
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 - Number of organs transplanted

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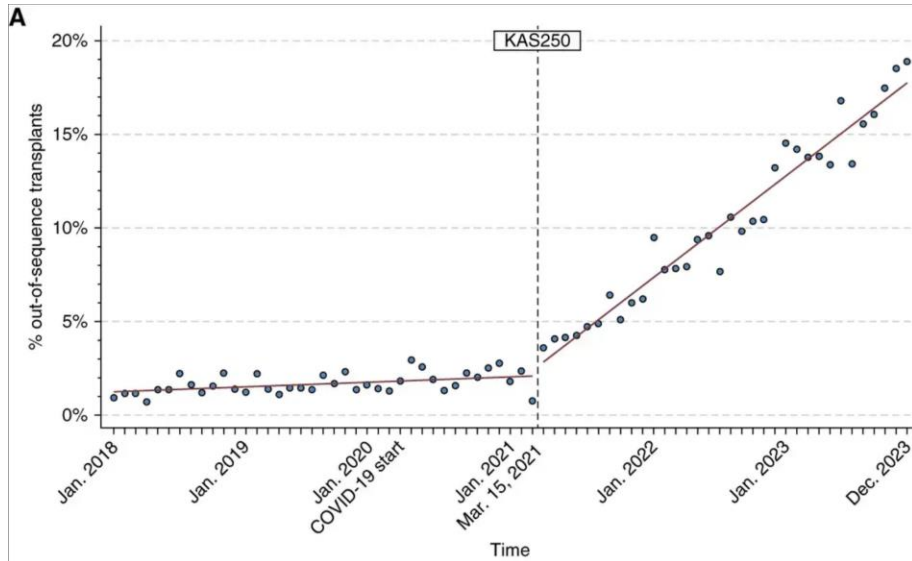
- 2020: Centers for Medicare and Medicaid Services (CMS) set new requirements for Organ Procurement Organizations (OPOs) based on
 - Number of organs procured --> More organs procured, with a higher proportion that are "high risk" or not suitable for transplantation
 - **Number of organs transplanted** --> More organs transplanted, with a higher proportion allocated out of sequence

Why?

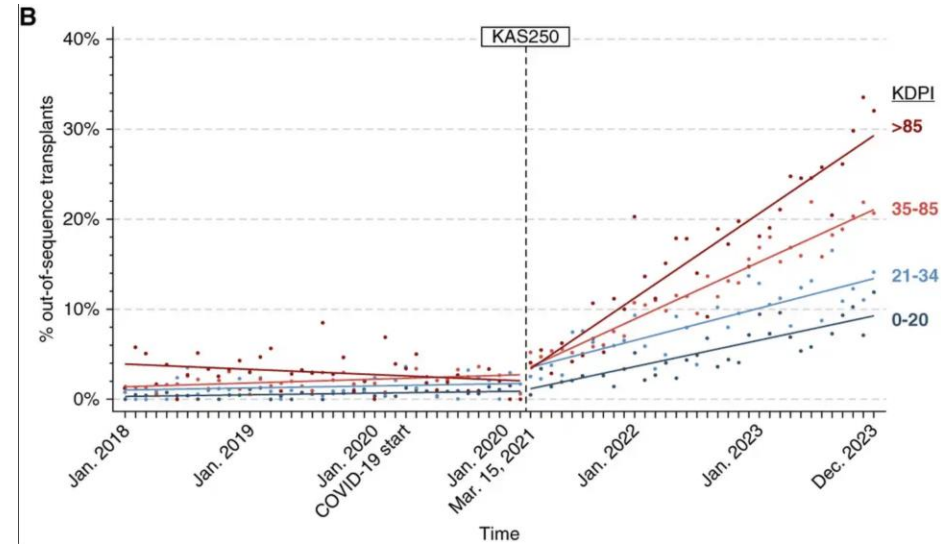
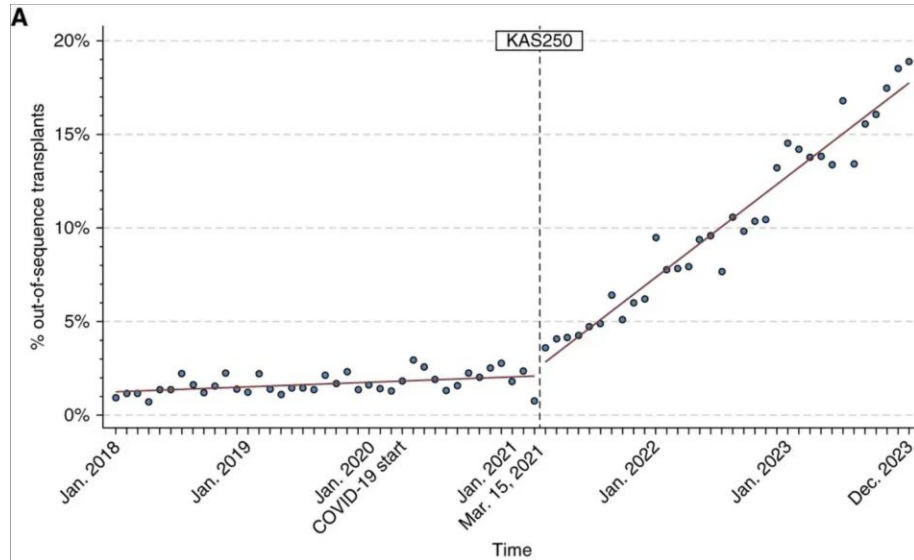
- 2020-23: Organ Procurement and Transplantation Network (OPTN; UNOS) reforms to facilitate broader geographic sharing of organs



Why?

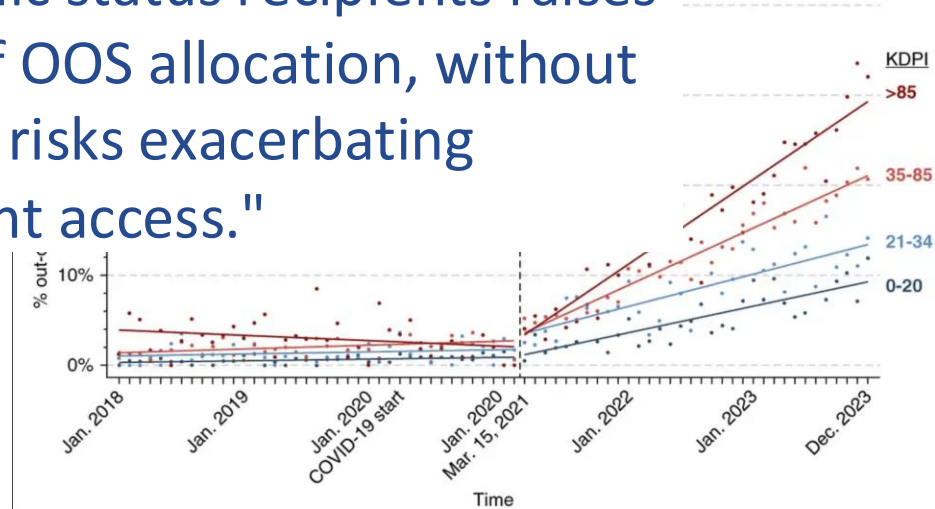
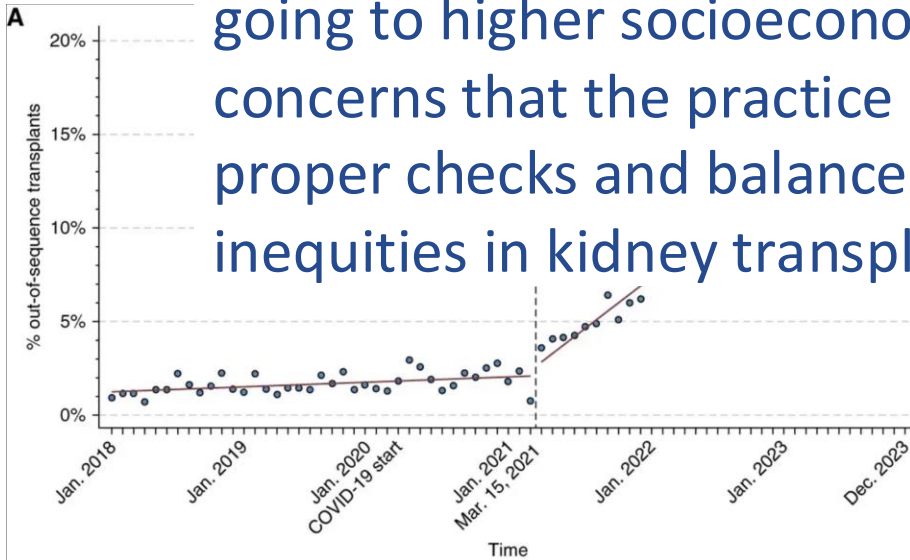


Why?



Why?

"the observation that OOS kidneys are more often going to higher socioeconomic status recipients raises concerns that the practice of OOS allocation, without proper checks and balances, risks exacerbating inequities in kidney transplant access."



In the News



The New York Times

GIVE THE TIMES

Account ▾

Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored

The sickest patients are supposed to get priority for lifesaving transplants. But more and more, they are being skipped over.

By [Brian M. Rosenthal](#), [Mark Hansen](#) and [Jeremy White](#) Feb. 26, 2025

[Leer en español](#)

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683

Marcus Edsall-Parr, a teenage kidney patient in Michigan, has been getting dialysis treatments for years. *Alyssa Schukar for The New York Times*

In the News



Organ Transplant System ‘in Chaos’ as Waiting Lists Are Ignored

The sickest patients are supposed to get priority for lifesaving transplants. But more

Disregarding the list has worsened some disparities. White people make up 39 percent of the organ registry, data shows. They have a leg up even in the normal process: Last year they received 46 percent of transplants. But when the list was ignored and patients were skipped, they got 50 percent.

In the News

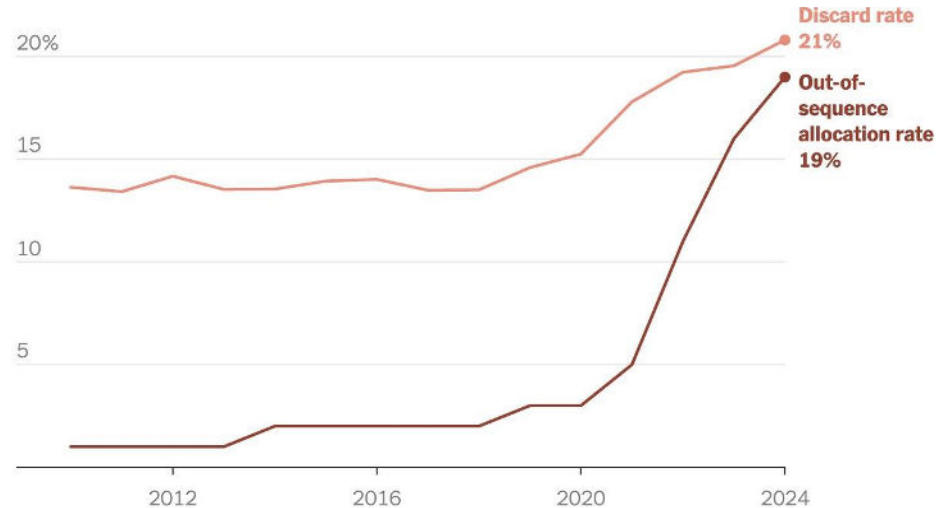


The New York Times

GIVE THE TIMES

Account ▾

Skipping patients has not improved organ discard rates



Source: Based on Organ Procurement and Transplantation Network data as of Jan. 17. - By The New York Times

What's at Stake?

Justice

Procedural: Different candidates experience different "rules of the game"

Distributive: Some groups of candidates are advantaged/disadvantaged

Utility

More organs are being transplanted

Higher-risk organs are being transplanted

The Real World

OPOs and transplant centers face regulatory incentives to promote utility

Does allocation OOS undermine the public trust?

What's Next?

- Health Resources and Services Administration (HRSA) and the OPTN have created an AOOS Workgroup
 - Standardized definitions
 - Policy projects TBA
 - AOOS Dashboard [<https://www.hrsa.gov/optn/policies-bylaws/policy-issues/allocation-out-of-sequence-aos#learn>]
 - Updated Allocation Compliance Review and reports

Normothermic Regional Perfusion



- Who is dead?
- What is it?
- Why do it?
- Why is it in the news?
- What are the ethical issues?

Who is Dead?

- Uniform Determination of Death Act (UDDA):
 - (1) irreversible cessation of circulatory and respiratory functions,
or
 - (2) irreversible cessation of all functions of the entire brain,
including the brain stem

Who is Dead?

- Uniform Determination of Death Act (UDDA):
 - (1) irreversible cessation of circulatory and respiratory functions,
or
 - (2) irreversible cessation of all functions of the entire brain,
including the brain stem
 - A determination of death must be made in accordance with
accepted medical standards.

Who is Dead?

- UDDA & state laws tell us who is *legally* dead
 - This "death" is a legal construct
 - Definition and procedures *differ* across jurisdictions
 - Definition and procedures have *changed* over time
 - *But... it is really important to know who is dead under the law*

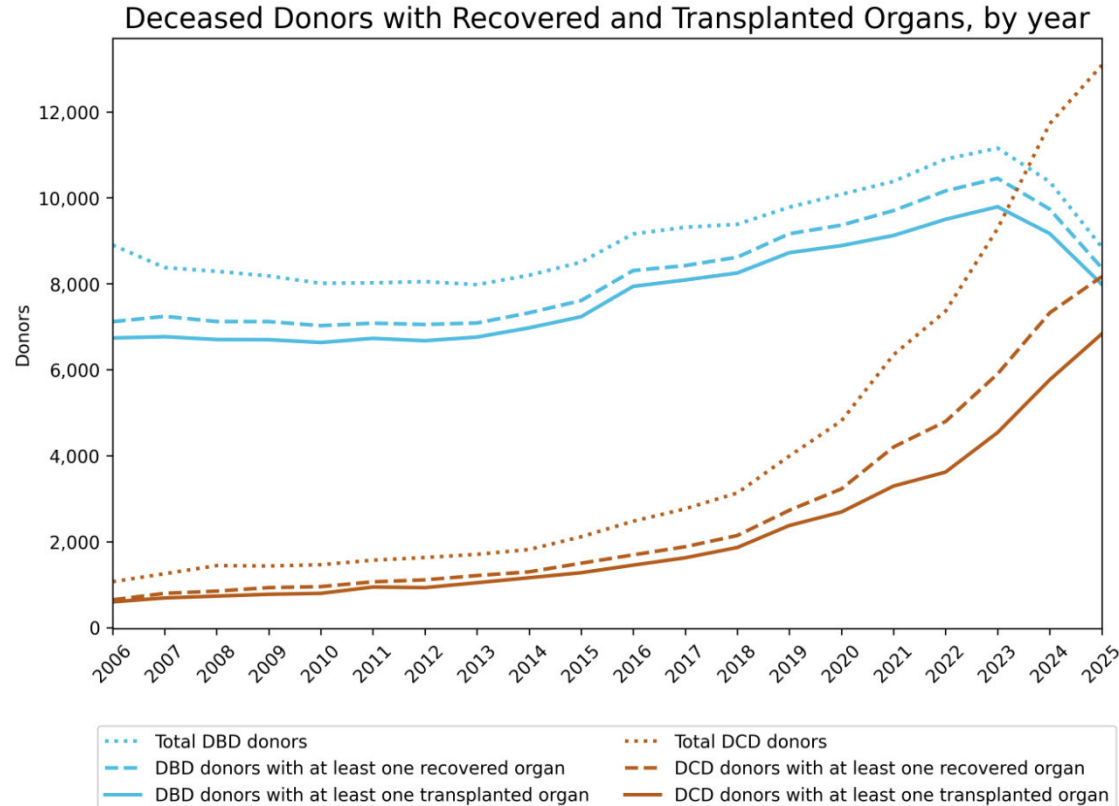
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 - *But... it is really important to know who is dead under the law*
- What tells us who is...
 - Medically dead?
 - Spiritually dead?

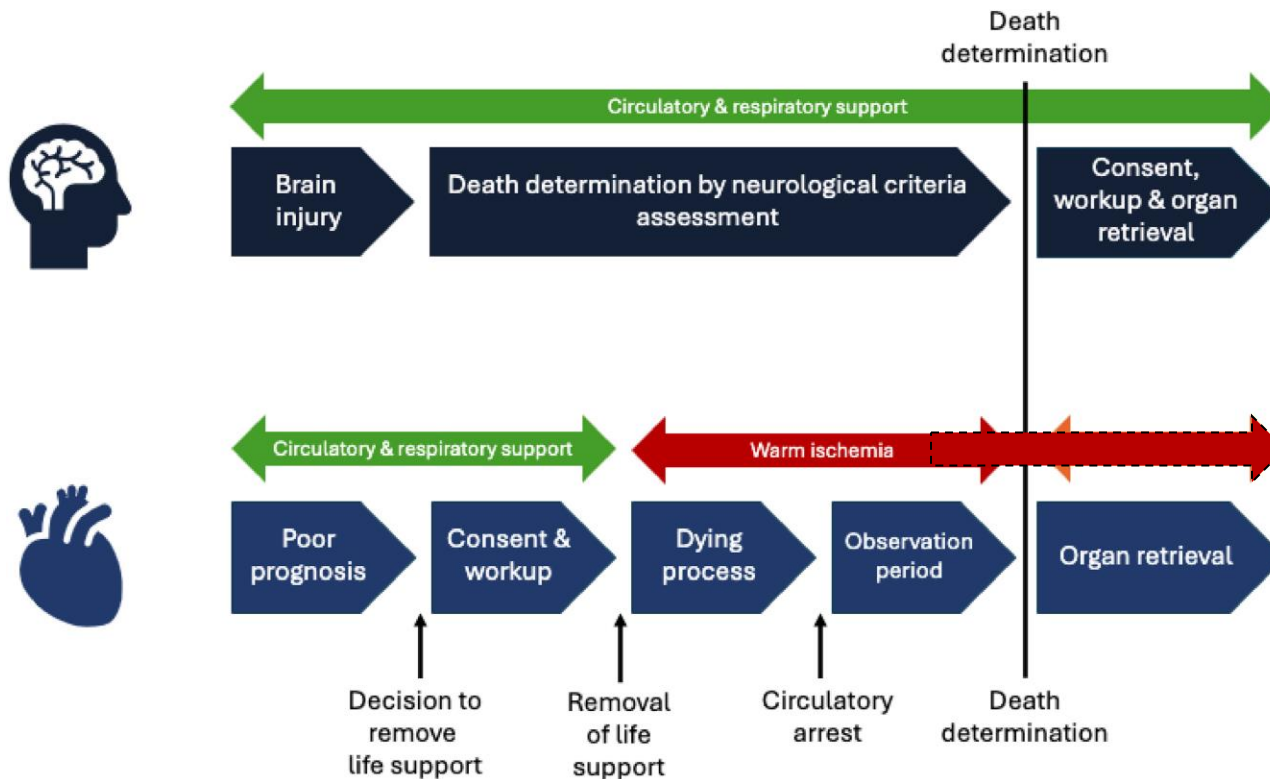
Who is Dead?

- Uniform Determination of Death Act (UDDA):
 - (1) irreversible cessation of circulatory and respiratory functions, -
-> **Donation after Circulatory Death (DCD)**
 - or
 - (2) irreversible cessation of all functions of the entire brain,
including the brain stem --> **Donation after Death by Neurologic
Criteria (DBD)**

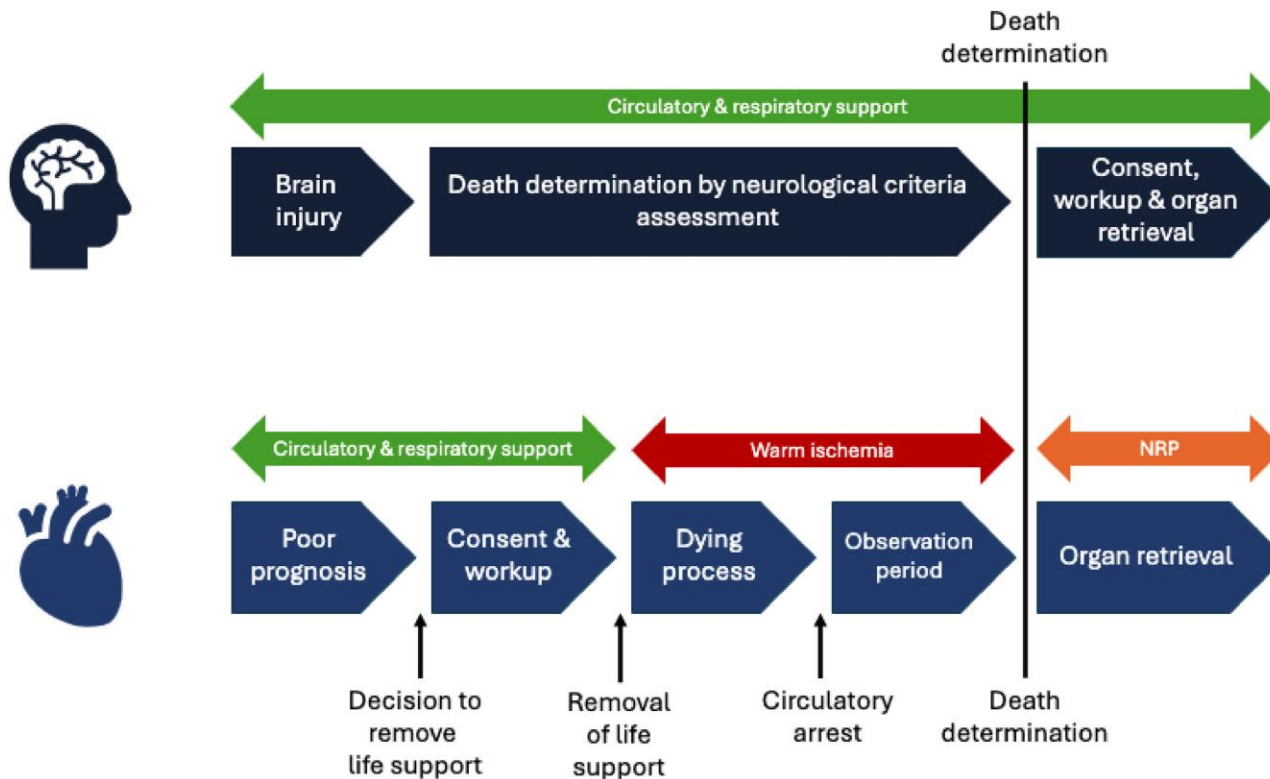
Who is Donating Organs?



NRP

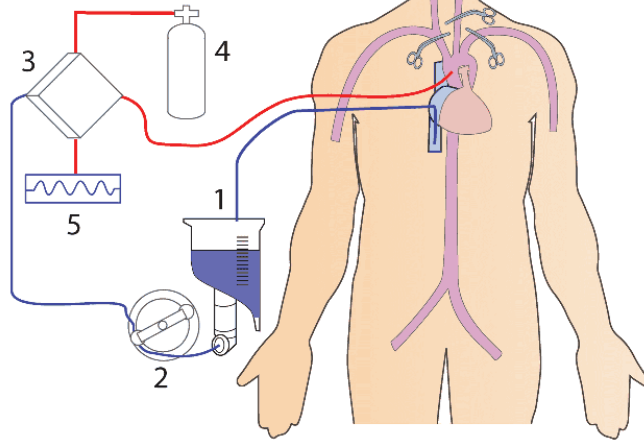


NRP



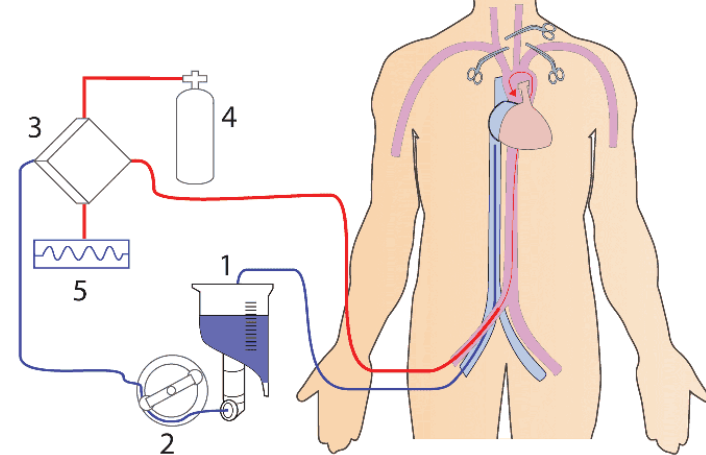
NRP

1. Reservoir
2. Roller Pump
3. Membrane Oxygenator
4. Gas Mixer
5. Heat Exchanger



Thoraco-abdominal normothermic regional perfusion

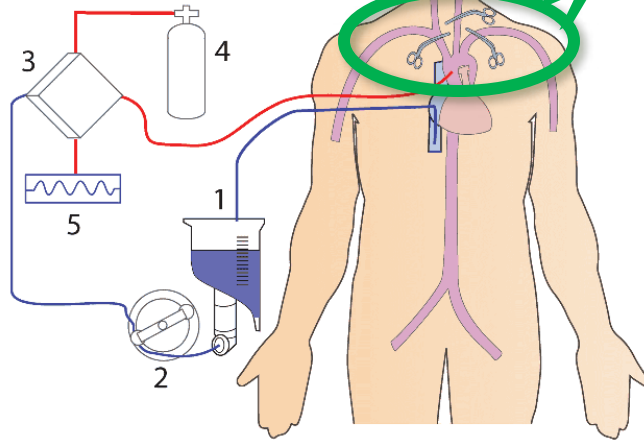
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Abdominal normothermic regional perfusion

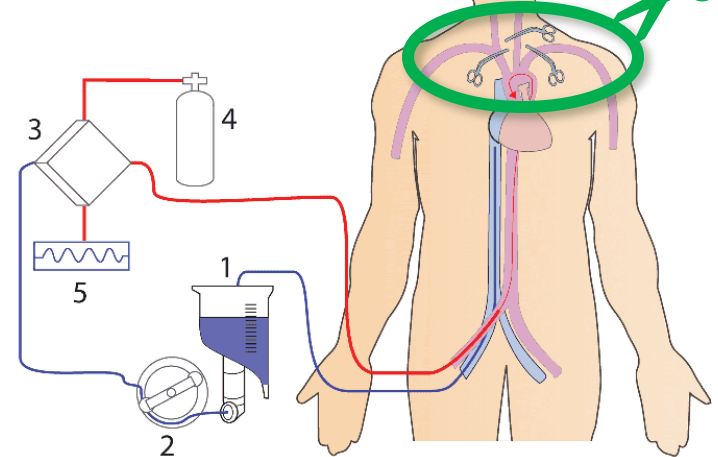
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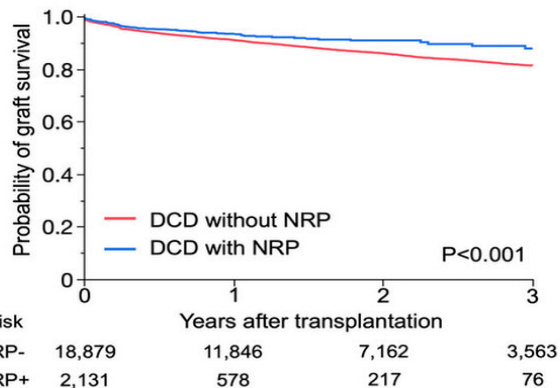
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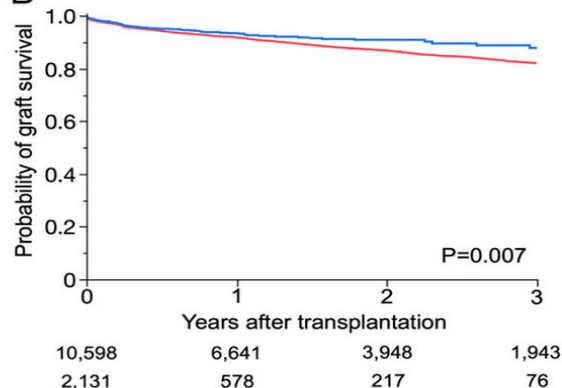
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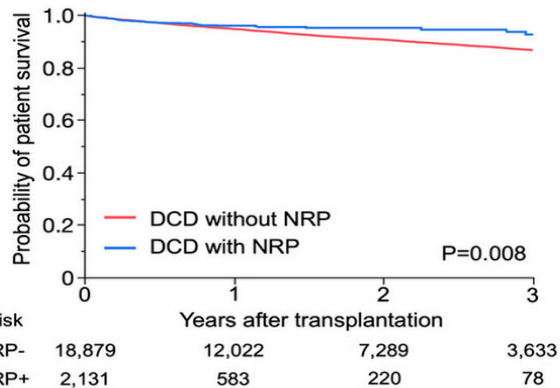
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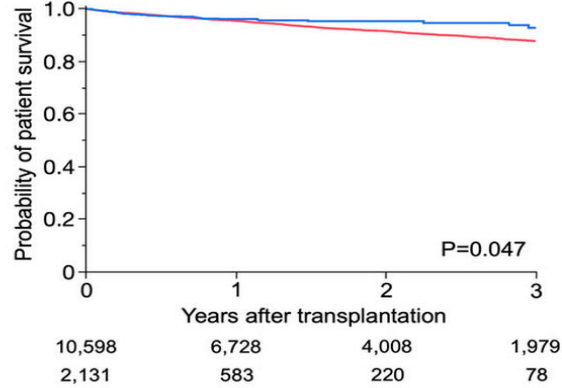
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"NRP was associated with reduced delayed graft function (30.3% vs 49.7%), shorter hospital stay (median: 4 vs 5 days), and improved overall graft and patient survival"

Why?

- More organs available for transplant
- Restores organ function after ischemia
- Organ function monitoring prior to procurement
- Better outcomes for transplant recipients, especially in higher-risk recipients

In the News





Shots

SHOTS - HEALTH NEWS

Doctors try a controversial technique to reduce the transplant organ shortage

JULY 8, 2024 · 5:44 AM ET

HEARD ON [MORNING EDITION](#)

 Rob Stein



[TRANSCRIPT](#)



The New York Times

When Does Life Stop? A New Way of Harvesting Organs Divides Doctors.

The technique restarts circulation after an organ donor is declared dead. But first surgeons cut off blood flow to the brain. One surgeon called it “creepy.”

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Dr. Nader Moazami, a surgeon at NYU Langone Health, has pioneered in the United States a new way of harvesting hearts from organ donors. Hilary Swift for The New York Times

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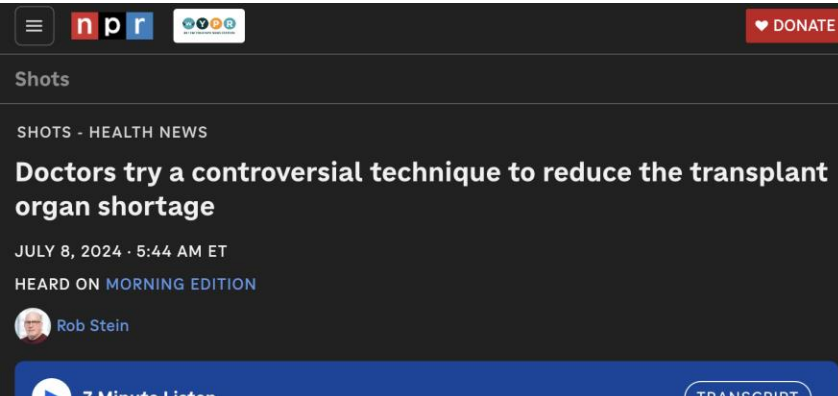


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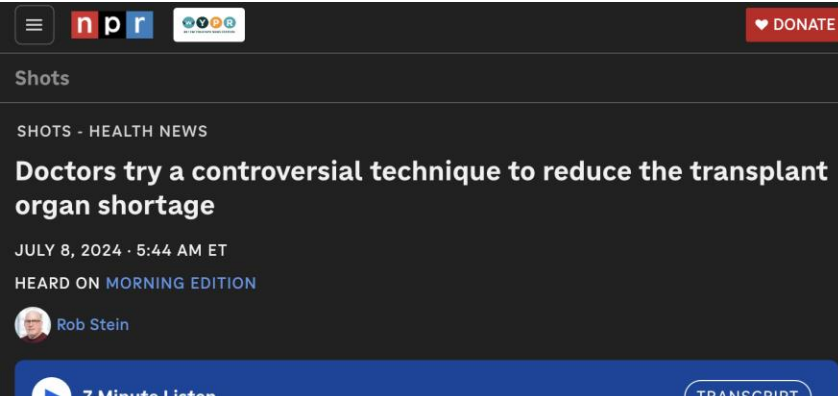


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What's at Stake?

Dignity and Respect

Is there any possibility of sensation or consciousness in the donor?

Is there any possibility of violating the "Dead Donor Rule?"

Does NRP *increase* the likelihood of honoring the donor's premortem wishes?

Utility

More organs are being transplanted

Better transplant outcomes*

*especially for higher-risk candidates

The Real World

Is NRP compatible with the legal definition of death?

Is NRP compatible with accepted moral or spiritual understandings of death?

Does NRP undermine the public trust?

What's Next?

- Health Resources and Services Administration (HRSA) and the OPTN have created an NRP Workgroup
 - Safety recommendations to "prevent unintentional reperfusion of the brain"
 - Guidelines for ensuring respect toward donors and families, and the donor/family experience

Xenotransplantation

- What is it?
- Why do it?
- Take my word for it, it's been in the news.
- What are (some of) the ethical issues?
- Will it cause the next pandemic?

Xenotransplantation

Genetically modified
embryo clones

Surrogate
birth

Designated
pathogen-free
environment

Continuous
evaluation

Anesthetized for
surgery

Organ
removed from
anesthetized
animal

Static cold
perfusion or
machine
perfusion

Animal
euthanized

Xenotransplantation



Specific sets of genetic modifications are proprietary. Animals and organs with different modifications are reviewed by the FDA as separate new innovations.



Xenotransplantation

Genetically modified
embryo clones

Surrogate
birth

Designated
pathogen-free
environment

Continuous
evaluation

Genetic modifications reduce the likelihood of rejection or organ damage when the pig organ is transplanted to the human recipient, but not so much so that the pig organ is better than/preferable to a human organ.

Anesthetized for
surgery

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euthanized

Xenotransplantation

Genetically modified
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evaluation

Designated Pathogen Free (DPF) facilities are free of *designated* pathogens, not designated to be pathogen-free.

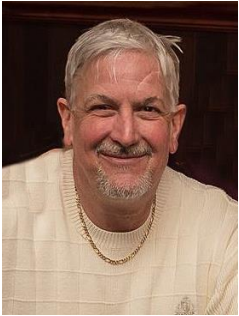
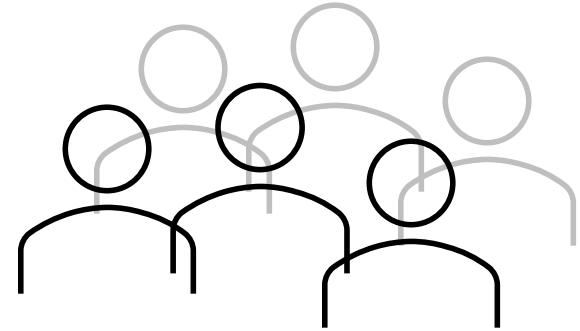
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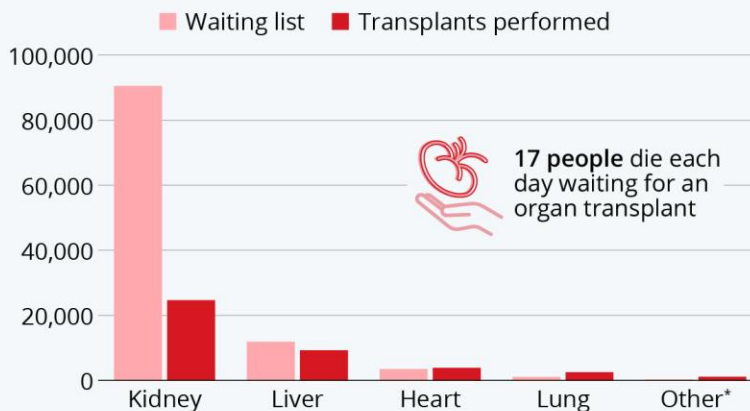
Xenotransplantation



Why do it?

The Organ Shortage Crisis in the U.S.

Number of patients on the waiting list versus patients that have received transplants in 2021, by organ



* Such as face, hands, and abdominal wall.

Source: Health Resources and Services Administration (HRSA)



Why do it, with pigs?

- Organs are similar in size and anatomy to human organs
- Litters of multiple offspring
- Reach maturity/suitable size for transplantation quickly
- Cost efficient to house/raise
- More favorable public perception than using primates
- Genetic distance decreases the likelihood of infectious disease spillover to humans

What's at Stake?

- **Pigs**
 - Animal welfare, ethical treatment of animals
- **Patients**
 - Patient safety, autonomy, and welfare
 - Fair candidate selection and allocation
- **Professionals**
 - Ethical conduct of researchers and other professionals
- **Policy**
 - Integration with existing allocation systems
 - Regulatory oversight, reimbursement, intellectual property

What's at Stake?

- Pigs
- Patients
- Professionals
- Policy
- Public health?

In the News

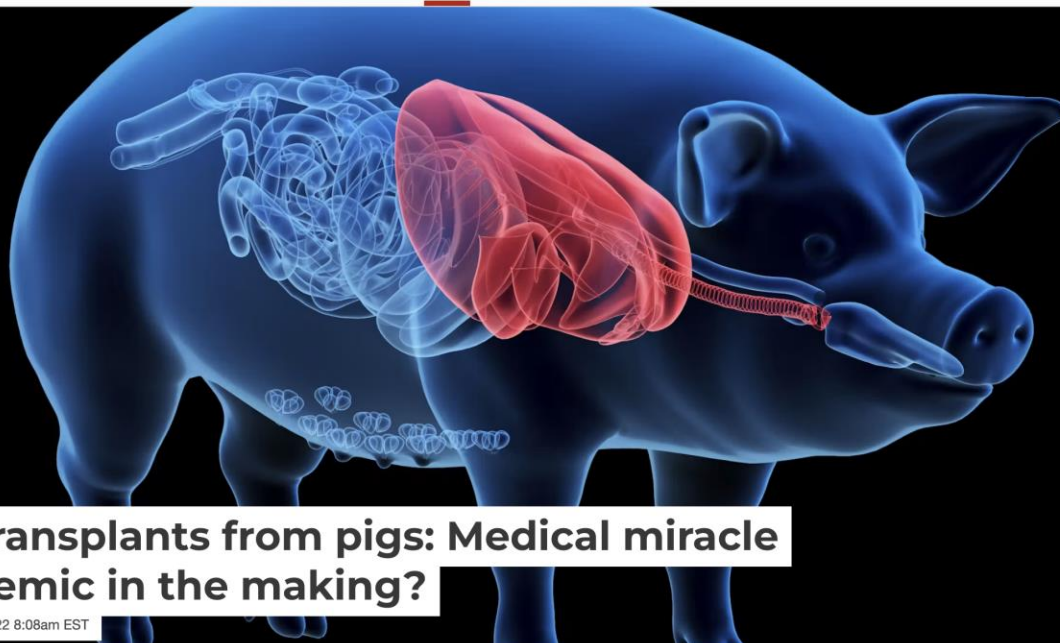
THE CONVERSATION

Academic rigor, journalistic flair

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Organ transplants from pigs: Medical miracle or pandemic in the making?

Published: February 27, 2022 8:08am EST

In the News

≡ Smithsonian *magazine*

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Porcine Virus May Have Led to the Death of First-Ever Pig Heart Transplant Patient

Doctors say this infection will likely be preventable in future pig heart transplants



Margaret Osborne | Science Correspondent

May 6, 2022

Porcine Cytomegalovirus (pCMV)

Can not spread to human cells (Species-specific)

Can only enter and copy itself inside of pig cells (in the transplanted xenograft)

Can damage the xenograft

Can trigger the human immune system to attack the damaged xenograft

While it is copying itself, makes proteins that cause inflammation and blood clotting

Xenotransplant recipients

- Xenotransplant recipients will be more broadly and more deeply immunosuppressed than allotransplant recipients



Xenotransplant recipients

- Xenotransplant recipients will be more broadly and more deeply immunosuppressed than allotransplant recipients



Xenotransplant Infection Control

Protect others

- Airborne isolation
- Negative pressure room (pulls air in)
- Care team consents to participate
- Care team porcine pathogen surveillance

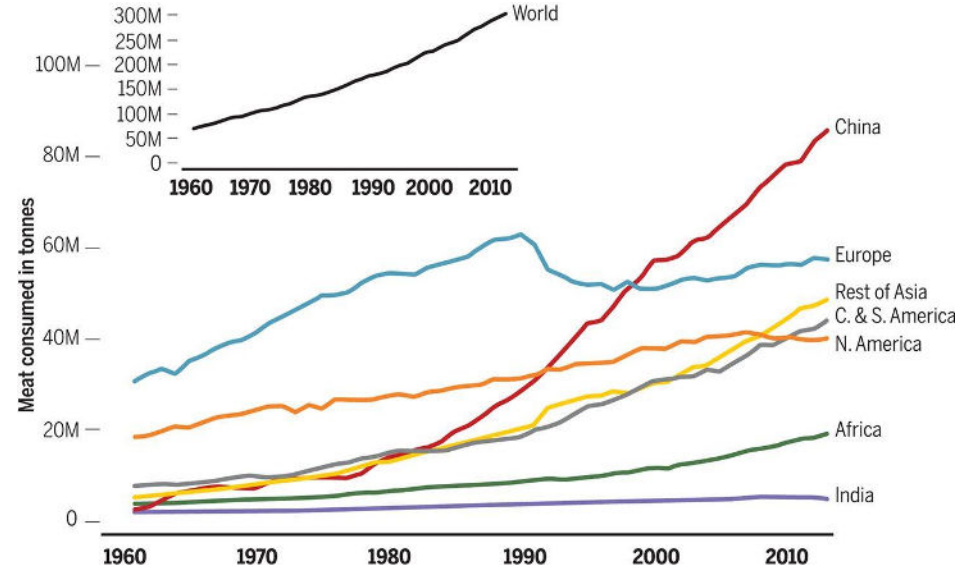
Protect patient

- Universal precautions
- Positive pressure room (pushes air out)
- Care team attests to no symptoms of infection
- Care team temperature/symptom surveillance

Unknown Unknowns

- The greatest risks from xenotransplantation are the risks to recipients
 - Complex evaluation and consent procedures
 - Uncertain outcomes
 - Intensive immunosuppression
 - Privacy
- The likelihood of a new infection spreading to humans because of xenotransplantation is minimal

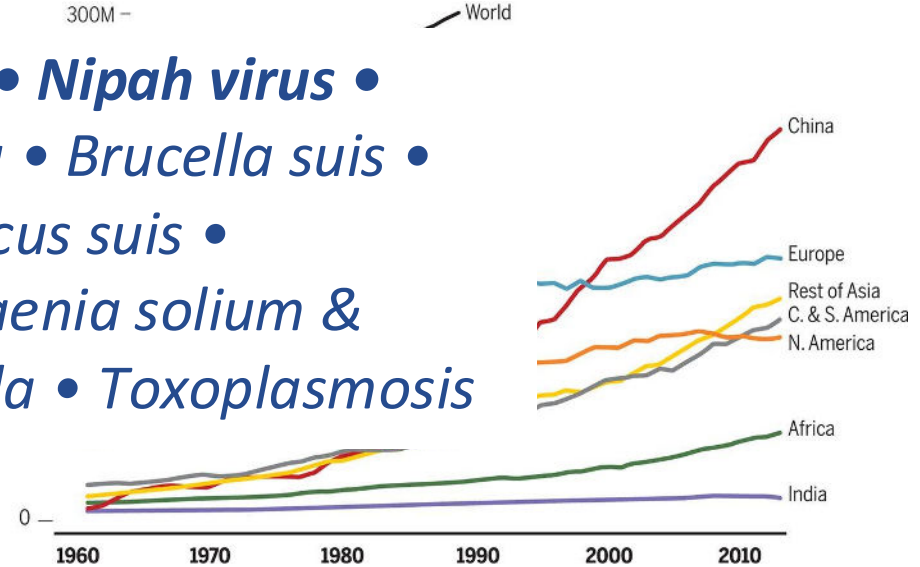
Unknown Unknowns



Unknown Unknowns



***Swine flu • Hepatitis E • Nipah virus •
Erysipelothrix • Yersinia • Brucella suis •
Tularemia • Streptococcus suis •
Salmonella • E. coli • Taenia solium &
cysticercosis • Trichinella • Toxoplasmosis***



Transplant Ethics

- Look for tensions among **utility, justice, and respect**
- And look for interactions with an imperfect world
- If the problem, responsible party, motivation, or solution seems *obvious*... make sure they got the whole story
- Or if it sounds *too good to be true*... make sure they got the whole story
- **Transplantation is better & more ethical with *your* input!**

<https://www.hrsa.gov/optn/policies-bylaws/public-comment>



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Thank you!

Olivia Kates MD, MA
Johns Hopkins University