

The ERA of Regulatory Oversight in Solid Organ Transplantation

Does Your Program Have the Right Stuff?



Improving People's Lives
through innovations in personalized health care

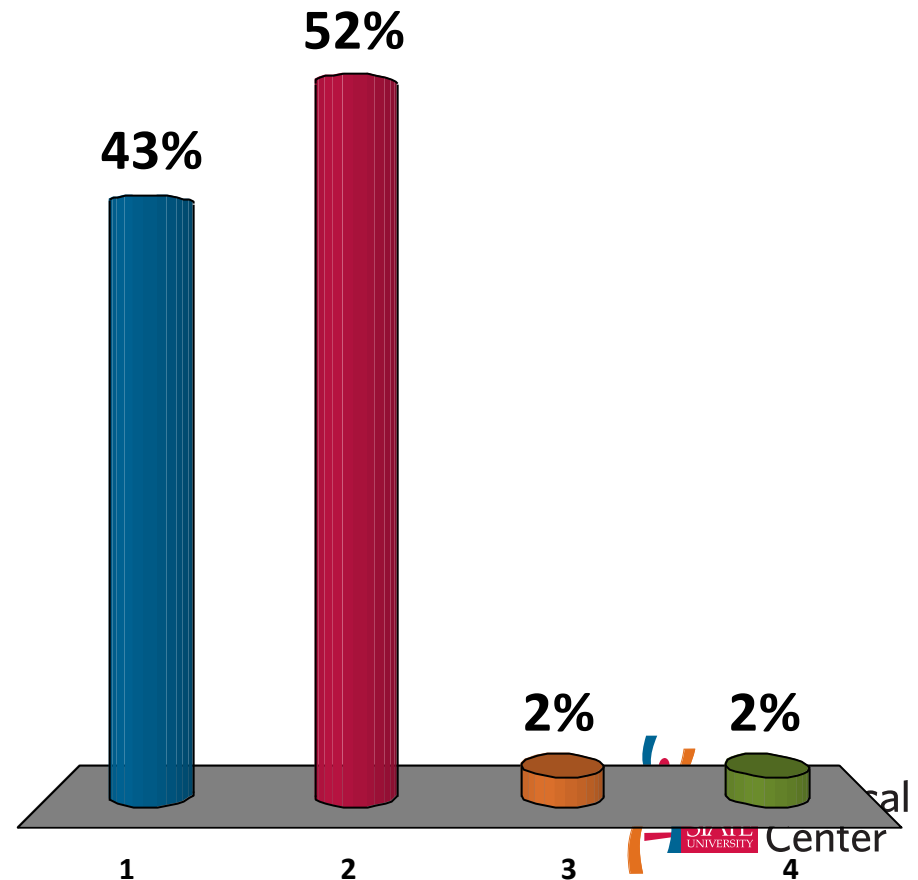


Disclosure Information

- No financial conflicts to disclose.
- (I am as confused as you are)

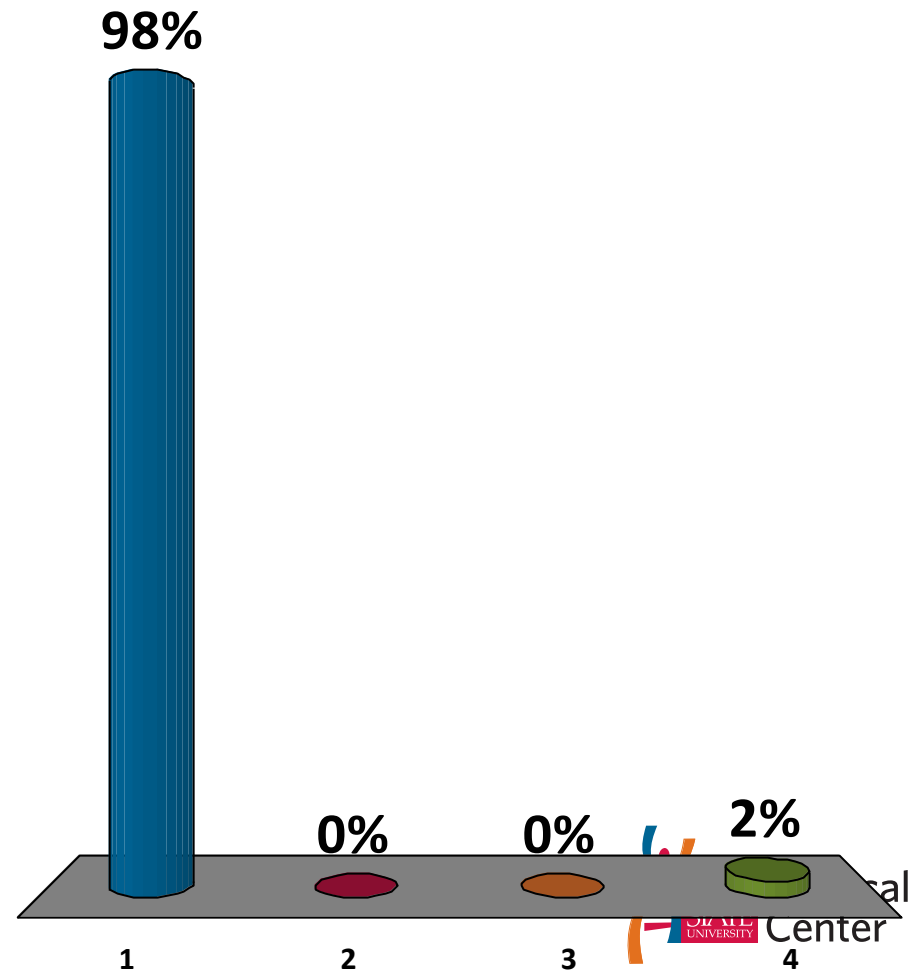
UNOS is a...

1. Part of the federal government
2. A contractor for transplant programs
3. A trade organization
4. United Network of Surgeons



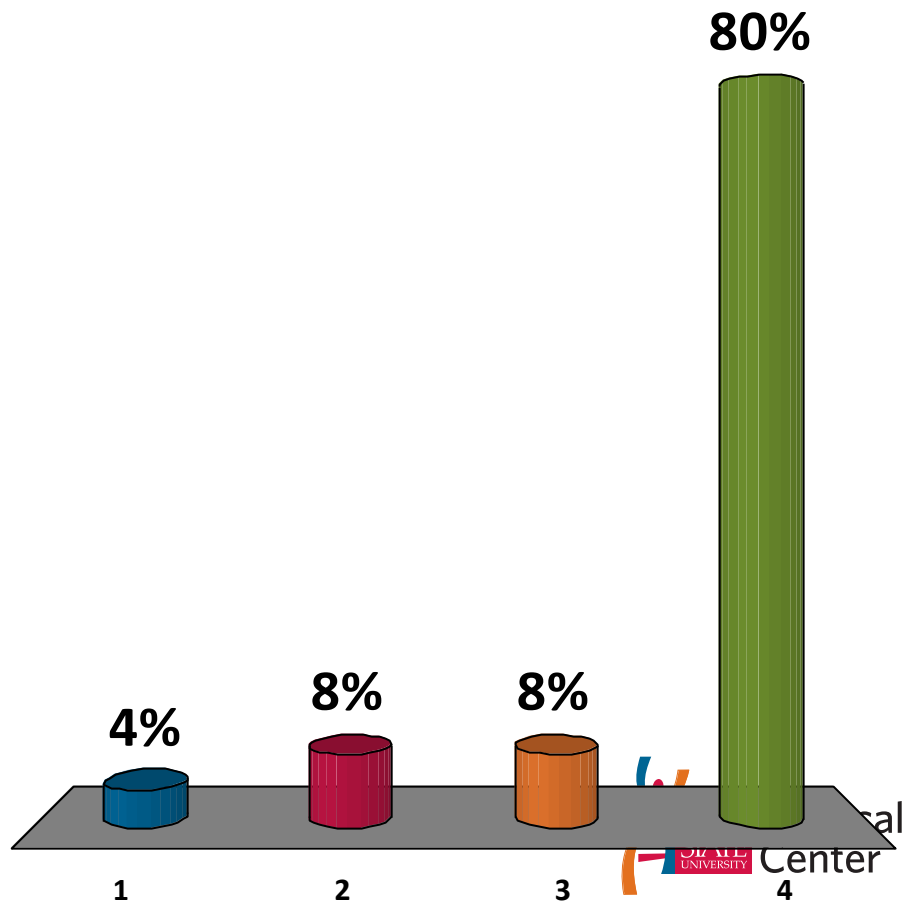
OPTN is...

1. Organ Procurement and Transplant Network
2. A unionized labor program
3. State-run transplant program
4. Organ Processing Tissue Network



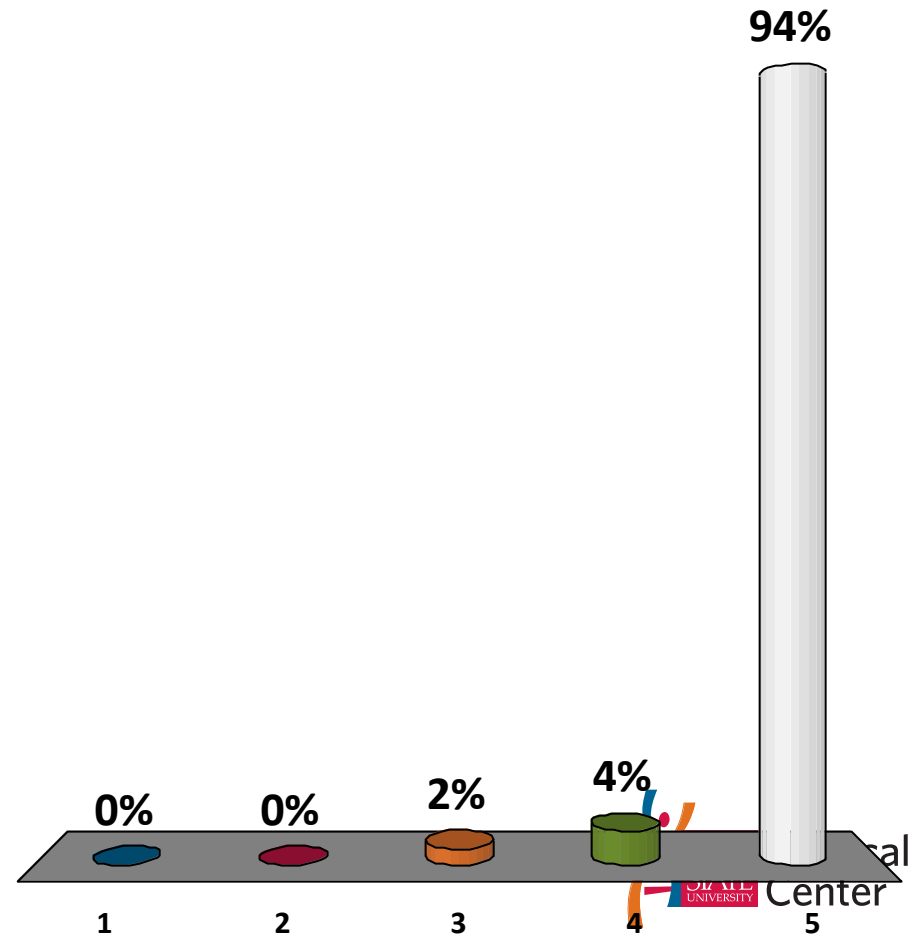
SRTR reports...

1. Only to patients and recipients
2. Makes policies governing transplant
3. Enforces the OPTN bylaws
4. Patient/organ survival after transplant



Insurance contracts are based on...

1. Cost of transplant at center
2. Length of stay
3. Quality metrics
4. Survival rates
5. All of the above



“The Right Stuff”

The Key to Transplant Success in the Current Regulatory Environment

- History-How did we get here?
- Current regulatory requirements
 - OPTN/UNOS
 - CMS
- Building a successful program
 - Quality assessment/Process Improvement (QAPI)

Iconic Role Models

“ Ask the Question”
Pharos, 1982



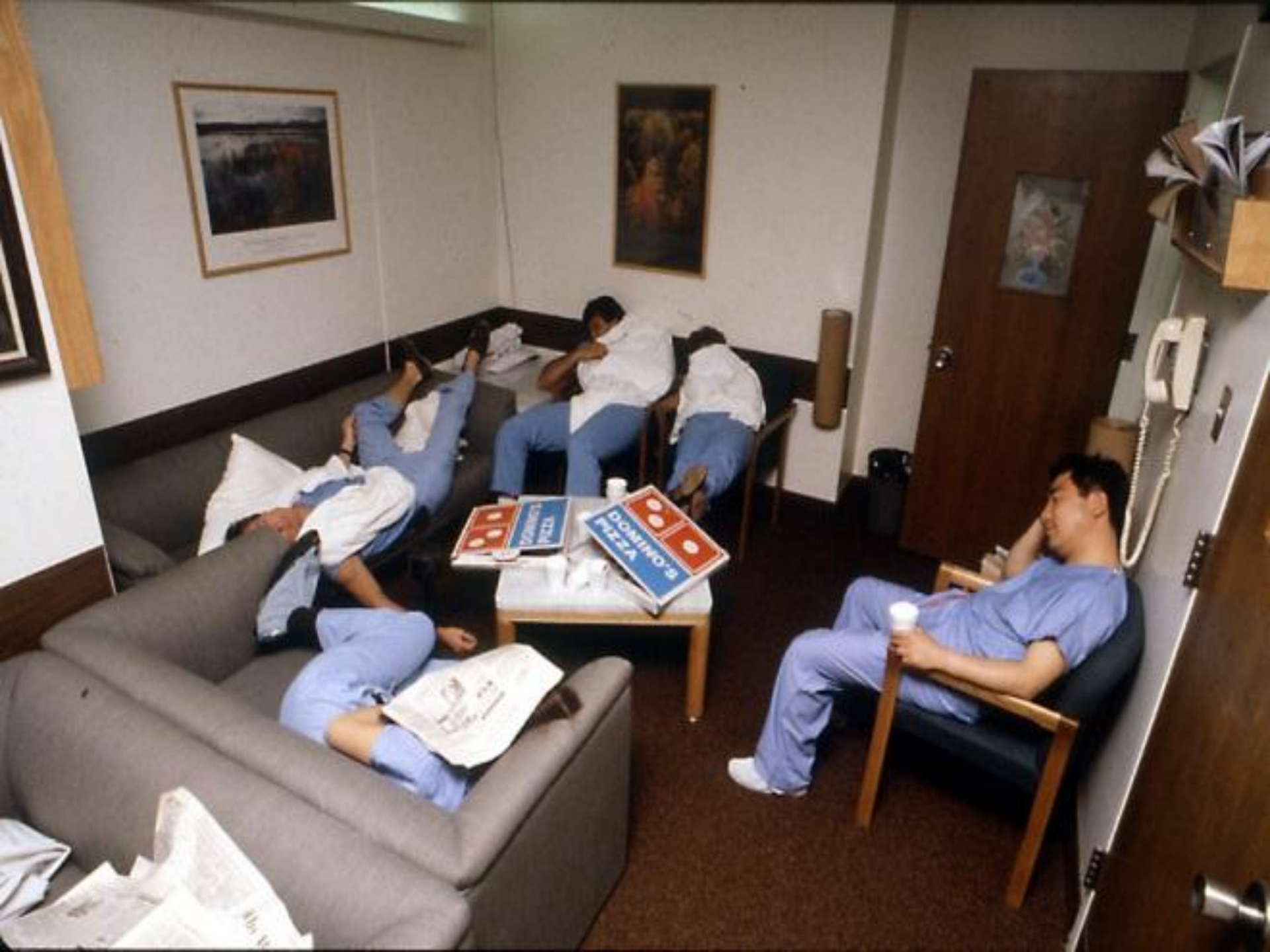
Ravitch

Starzl

Bahnson

“We do not learn from
vain exultation of
successes, but from
our failures.”
Many Sleepless Nights

“Be Brave”
Mens Room,
PresbyHosp Pgh.



TRANSPLANTATION- Quality and Quantity of LIFE

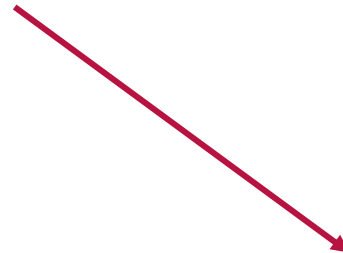


Transplant Success

GOOD DONOR



GOOD RECIPIENT



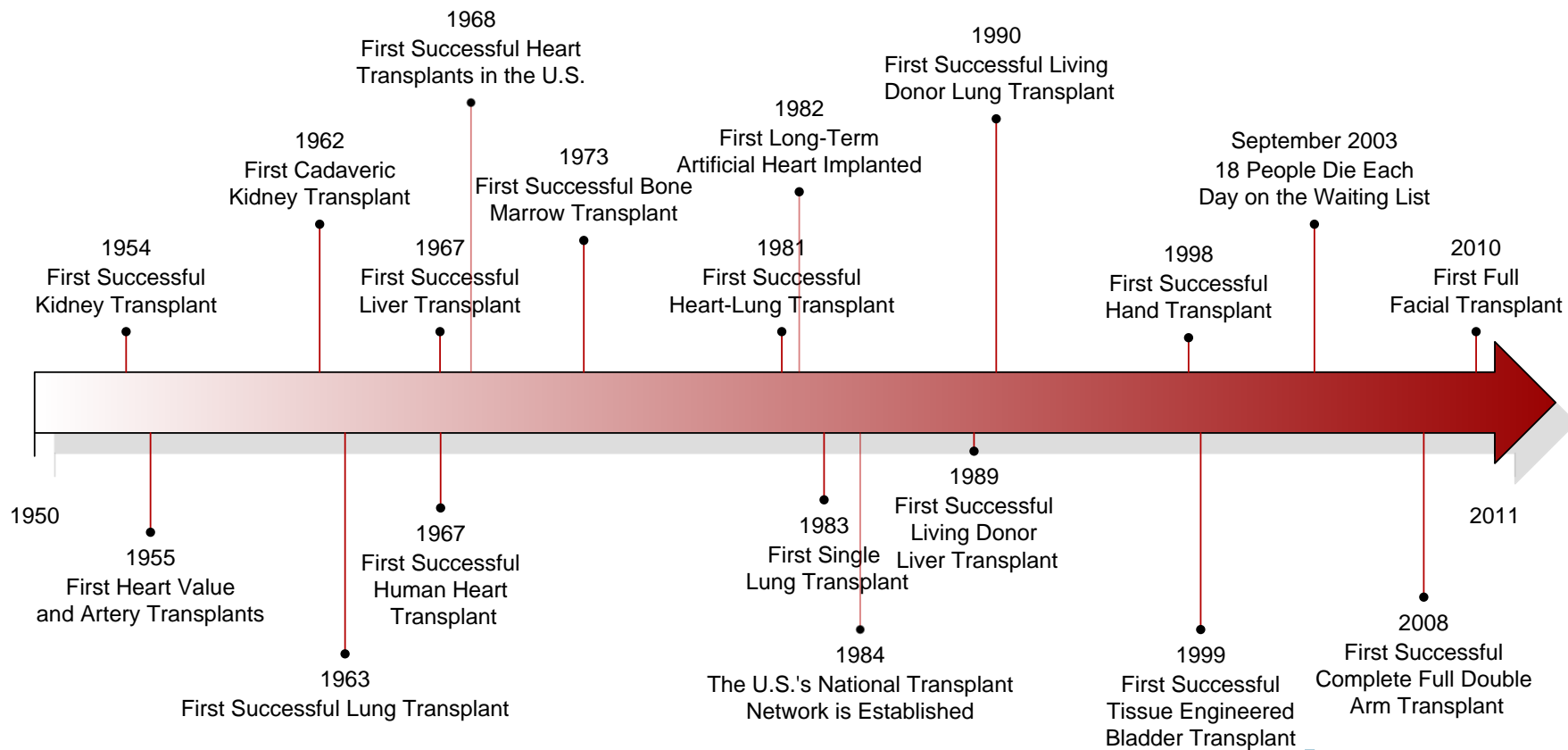
GOOD OUTCOME

The Regulatory oversight of Transplantation...*it's Alphabet Soup!*

ASTS Heart OPO Lung UNOS
CMS Arm SRTS
Face **HRSA**
NATO ACO ACOT
Hand NKF HHS
NOTA AOPO DOT Kidney **OPTN**
Bone Marrow
JCAHO AST Liver

Transplant History

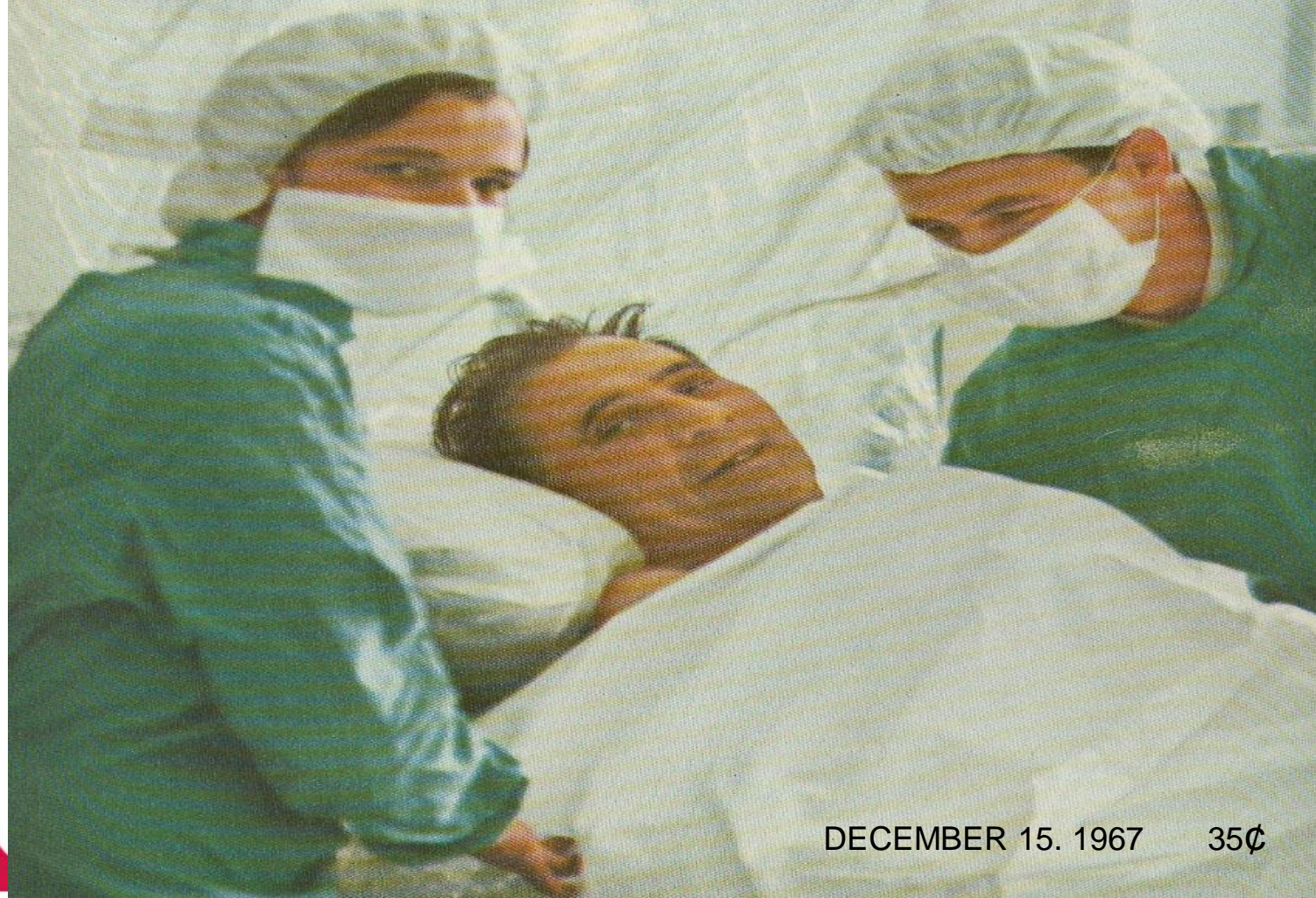
Fantastic Firsts in Our field



LIFE

GIFT OF A HUMAN HEART

A dying man lives with a dead girl's heart



Louis Washkansky, recipient of the historic transplant, smiles after regaining consciousness

DECEMBER 15, 1967

35¢



Development of Heart Transplantation

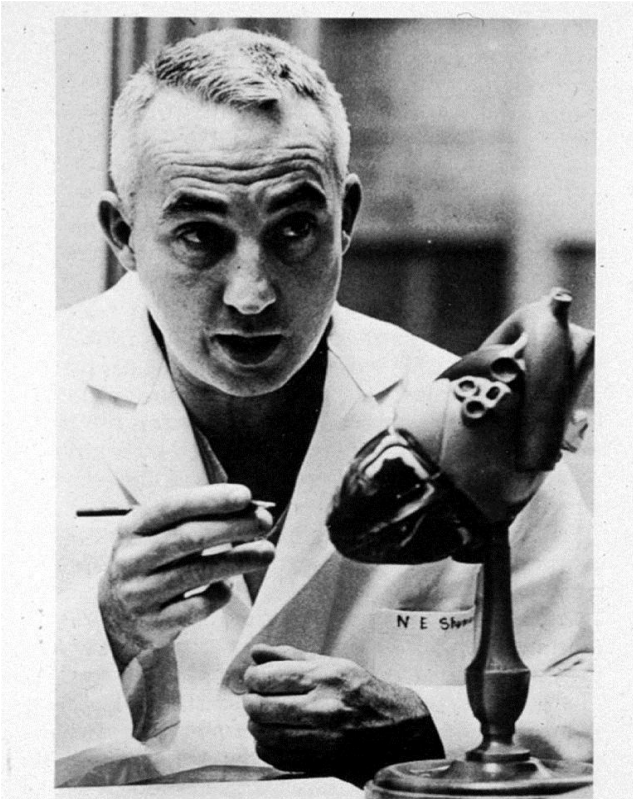


Figure 1–8. Norman Shumway, regarded by most investigators as the major contributor to successful heart transplantation, is shown here in 1968, soon after his initial human heart transplant procedure.

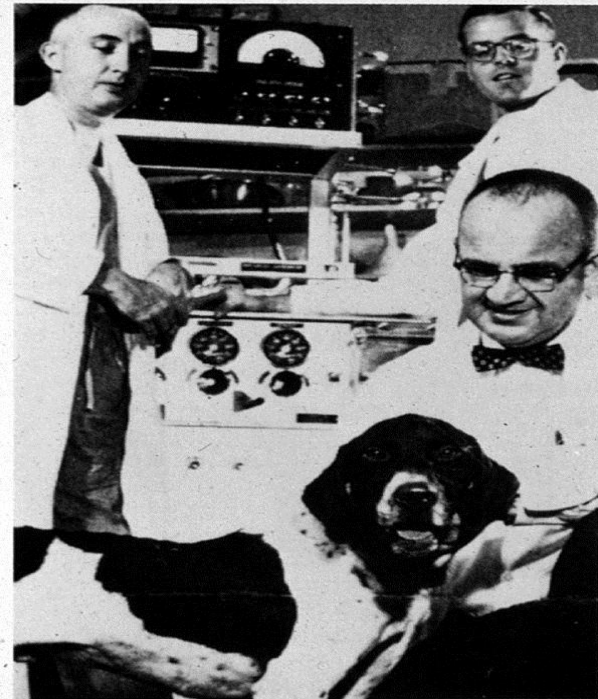


Figure 1–5. Principals in the experimental laboratory at Stanford University in 1960. Norman Shumway (*left*), Richard Lower (*right*), and Raymond Stoffer (*right lower*) with a long-term surviving dog heart transplant patient.

reality at the University of Capetown in South Africa.

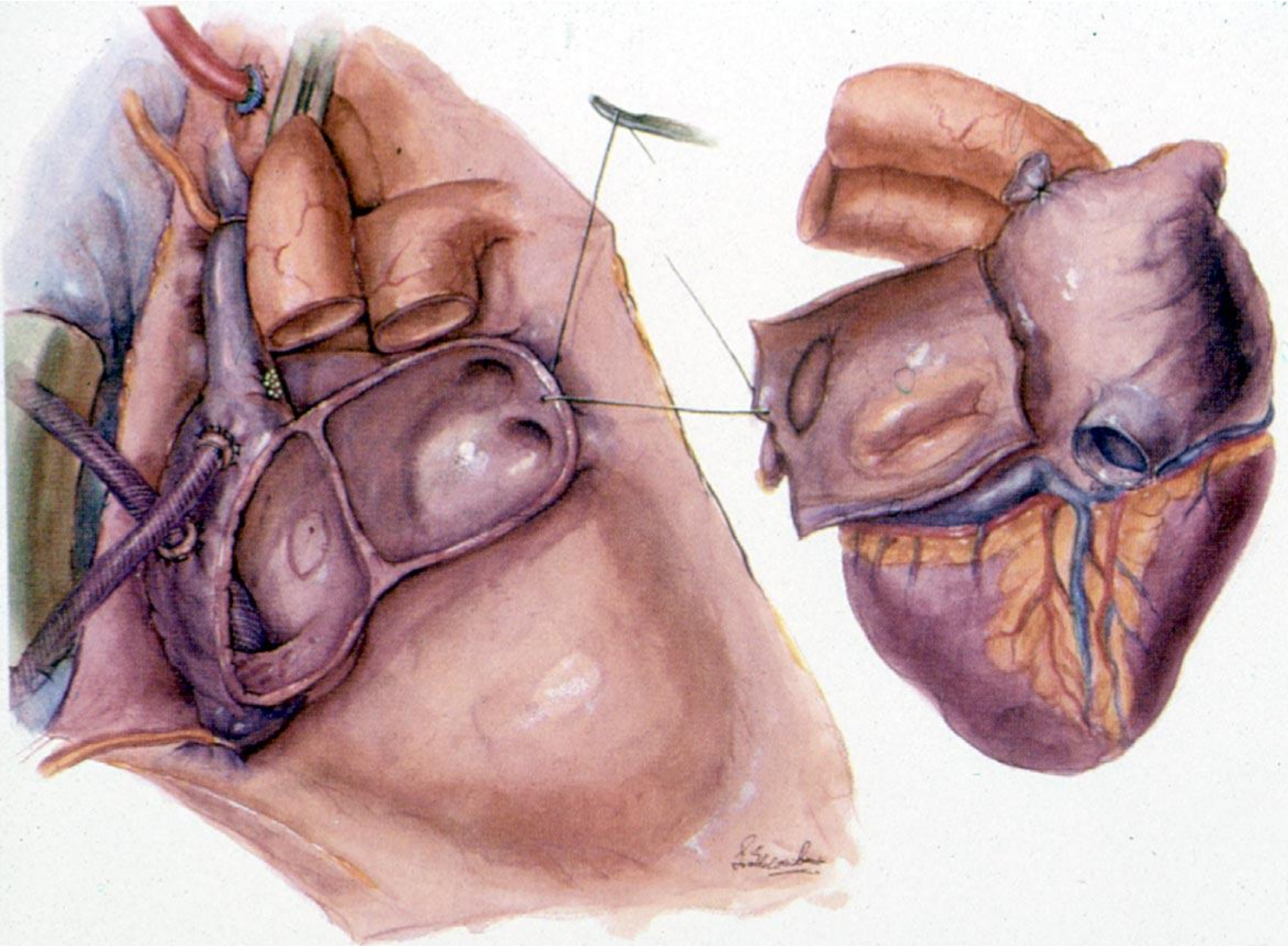


Figure 12-8. The implantation procedure is begun with the left atrial anastomosis.

Time Line: William Tucker v. Dr. Richard Lower et al

-----**May 24, 1968**-----**May 25th** ----- **May 25th**
6:05pm **2:05am** **9:30am**

Admitted to MCV
Unconscious unaccompanied by
Family or friend

Tracheotomy

discuss transplant
ME present

May 25th ----- **May 25th**----- **May 25th** -----
1:00pm **2:00pm** **3:45pm**

Neurological consult
EEG flat, exam
“brain death”, stable VS

Dr. Hume seeks ME
Permission to release
“unclaimed body”

No family found
ME releases body

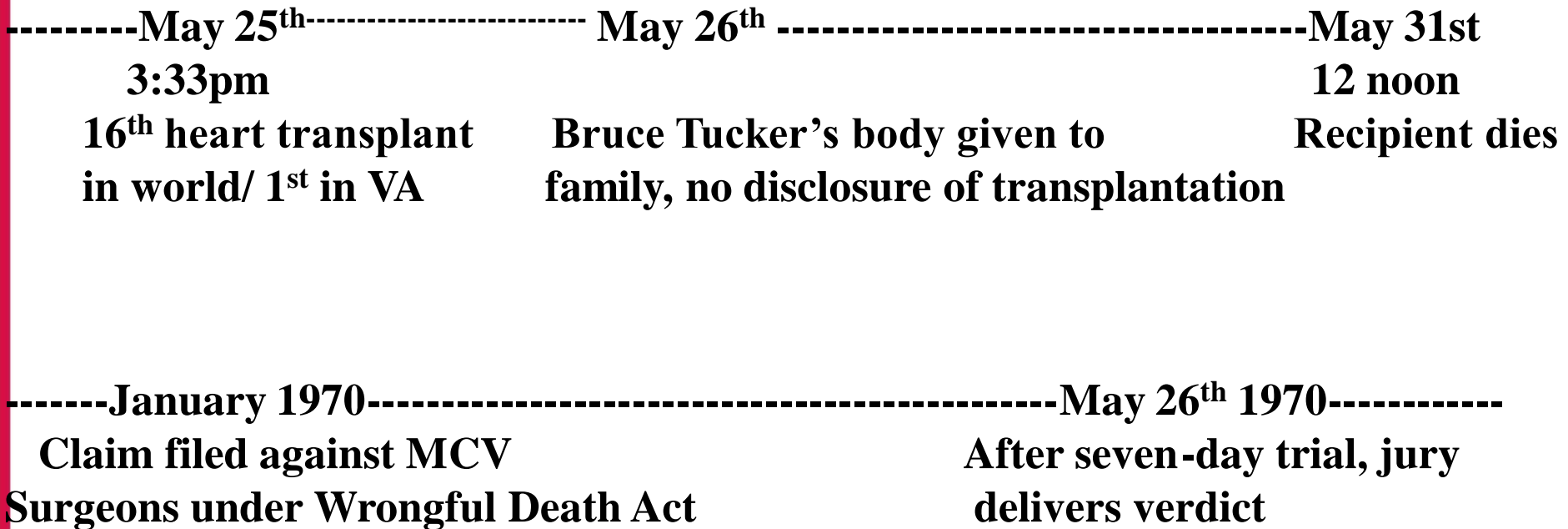
[-----**May 25th** -----]

1:45pm-3:00pm
Friend of Tucker Family
Makes inquiry a hospital information
Desk...no information given

Name of brother, business address, phone #
found in Tucker’s wallet



Time line: William Tucker v. Dr. Richard Lower et al



At Issue

- Was Bruce Tucker legally dead when Dr. Lower removed his heart?
- Did Dr. Lower kill Tucker by removing his heart?

THE RICHMOND NEWS LEADER

THURSDAY

MAY 25, 1972

PAGE 13

'Key Question for Jury' Is 'Moment' of Death

By JIM MASON

A seven-man Law and Equity Court jury was expected to begin deliberating later today on a verdict in the heart transplant case.

And its verdict is likely to turn on the jury's answer to the key question in the trial: When did Bruce O. Tucker, the donor in Virginia's first heart transplant, die?

Was it when his brain ceased functioning, some three hours before his heart was transplanted, as doctors

argued that the words "defined by physicians" imply that the legal concept of death is based on the definition of death by physicians.

Accordingly, as the physicians' definition changes, so too must the legal definition" Russell contended.

Assistant Atty. Gen. Theodore J. Markow, who represents the other defendant in the case, a doctor who formerly was on the staff of the chief state medical examiner here also touched on this

yers'arguments and refused their motion to dismiss the suit. Any change in Virginia law, which would incorporate brain death as a criterion of legal death, must be made by the legislature, not the courts, the judge said.

In addition to the medical and legal definitions of death, references have also been made during the course of the trial to "biological" and "theological" death.

Biological death, as ex-

The Weather

Today: Clearing.
High in 70s.

Tomorrow: Fair.

Local Data on Page B-1
122nd Year
Volume 114

Richmond Times-Dispatch

Richmond, Virginia, 23219

Virginia's State Newspaper

Friday, May 26, 1972

142,489

Virginia's
Largest
Newspaper

10 Cents

Medical Definition of Death Upheld in Transplant Case

By JAMES N. WOODSON

A temporary medical definition of death of a person as being brain dead was upheld in its first known test here yesterday by a jury of men, who returned a verdict that transplant surgeons at the Medical College of Virginia played no role in the death of a donor in a 1968 heart transplant operation.

The decision, which the plaintiffs attorneys indicated would be appealed, is expected to have medical and legal ramifications around the nation since it represents a laymen's affirmation that the question of medical judgment is a question for medical judgment rather than strictly a legal definition.

The decision also indicates that the seven-man and Equity Court jury accepted the cessation of the brain instead of cessation of heartbeat, respiration, blood pressure and temperature as the criteria for human death.

THE JURORS deliberated only 47 minutes in reaching their decision at the end of a seven-day trial, believed to be the first anywhere on a lawsuit alleging wrongful death of a donor in a heart transplant. The plaintiff, a Richmond shoe repairman, William E. Tucker, had filed the suit as administrator of the estate of his deceased brother, Bruce O. Tucker, a 54-year-old laborer here and the donor in Virginia's first heart transplant on May 25, 1968 at MCV.

Bruce Tucker entered MCV Hospital on the night of May 24, 1968, with massive head injuries sustained in an accidental fall.

Doctors at the hospital said Tucker died the next day, some hours before the transplant, of fatal brain injuries received in the fall.

But William Tucker alleged that the

respiration, pulse, blood pressure and body temperature.

Russell said afterwards: "The verdict of the jury clearly indicates that not only were these physicians innocent of any wrongdoing, but also it's a clear indication that the time and determination of death are judgments basically within the province of the medical profession."

"As to this particular case," he added, "it said the doctors were right as to the time Bruce O. Tucker ceased to be a person or an individual, which was when his brain totally and irreversibly ceased to function."

State Sen. L. Douglas Wilder, Tucker's lawyer, said the legal definition of death first adopted by Judge A. Christian Compton when he rejected a defense dismissal motion two days ago "is, we submit, the correct definition of

evidence and relies chiefly upon medical testimony."

IN AN UNEXPECTED, last-minute move yesterday, Judge Compton broadened the definition of death that he ultimately gave the jury as applicable law in the case, including the medical as well as the legal definition and allowing the jury to choose either of the two or a combination of them.

Wilder said, "It's awfully difficult to fly in the face of the system. Doctors are presumed to be doers of good and people picture them in their white coats with no potential for wrong."

"And yet," he added, "medical history is replete with instances of malpractice, though the proof required is so often impossible to come by. The closed fraternity rules out any ex-

ception that didn't "highly respect the medical profession."

"We have not sought to demean men of science and the medical profession," he noted, "but to portray what is and what should be."

Bruce said "Even if we didn't accomplish anything from a financial standpoint (Tucker was seeking \$100,000 in damages), we have set some guidelines for future medical conduct and I'm quite certain this type of conduct wouldn't happen again."

"We never questioned ability or professional standards," he added, "but the manner in which Bruce Tucker's case was handled did not, in my opinion, come up to the type of conduct you would expect."

That instruction said the time of death is when life ceases, a "ceasing to exist" that isn't continuing but occurs at a precise time that must be established according to the facts in each specific case.

In determining the time of the death in the Tucker case, the jurors were told that they could consider several elements, any one or more of which they might feel from the evidence to be controlling.

Those elements were: "the time of the total stoppage of the circulation of the blood; the time of the total cessation of the other vital functions consequent thereto, such as respiration and pulsation; the time of complete and irreversible loss of all function of the brain; and, whether or not the aforesaid functions were spontaneous or were being maintained artificially or mechanically."

Heart Transplantation

Rags to Riches . . .

Timeline

- 1960 - Lower and Shumway describe surgical technique in dogs. Surg Forum 11:18, 1960**
- 1967 - Christian Barnard performs first human to human heart transplant in 54 year old man with severe heart disease**
 - *24 year old donor injured in car accident; removed from respirator and heart removed after it stops***
 - Patient succumbs 18 days after surgery 2° to pneumonia**
- 1968 - Shumway performs first heart transplant in U.S.**
- 1968 - 102 transplants performed at 52 centers**
 - 30% (30/108) alive at 12 weeks after surgery**
- 1981 - Cyclosporine immunosuppression introduced**

Heart Transplantation

“Growing Pains”

Questions raised by early experience

1. What about the donor?

Was she dead or did we facilitate death?

What are the criteria of death?

2. Who should perform transplants

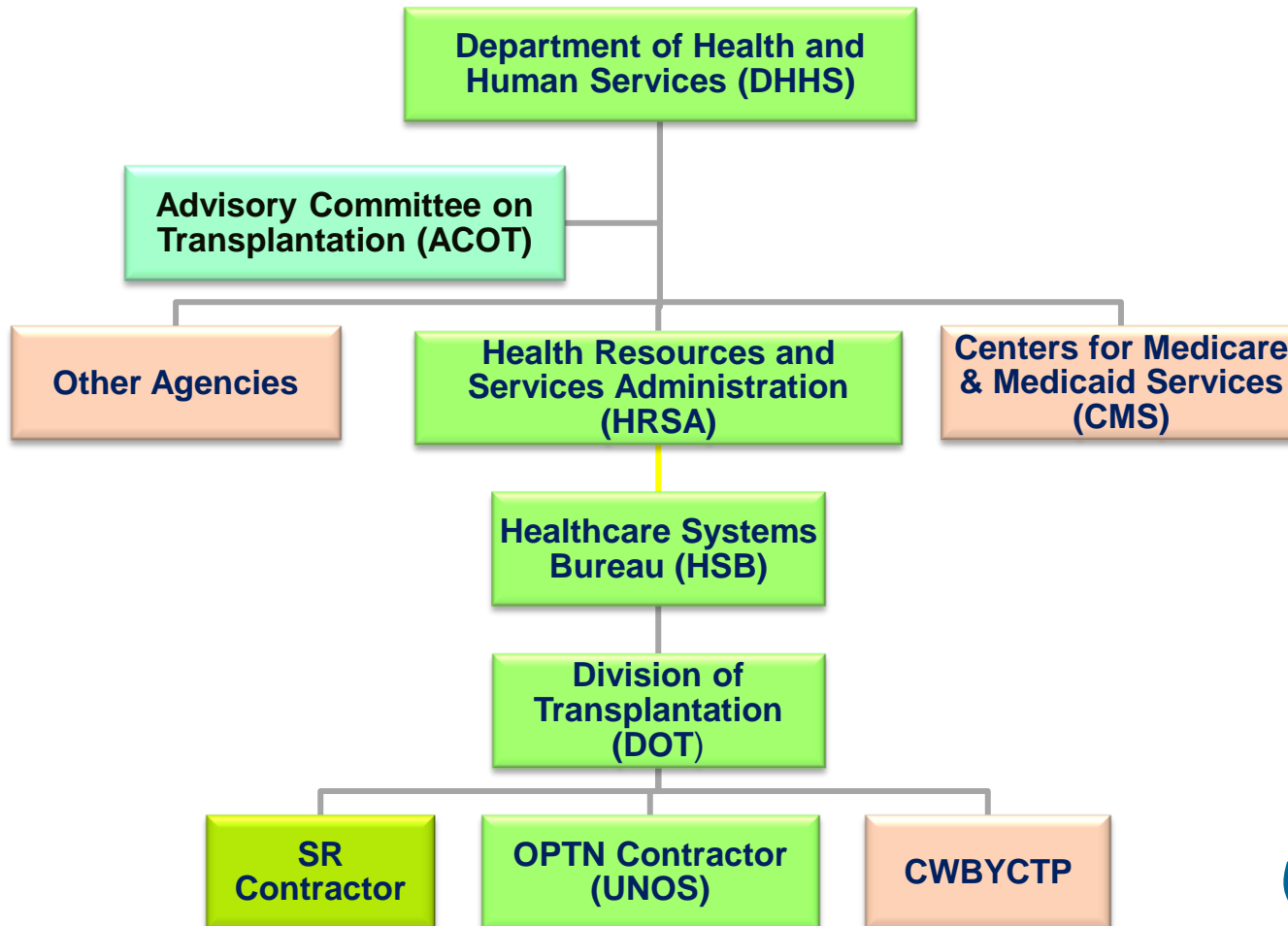
Where should they be done?

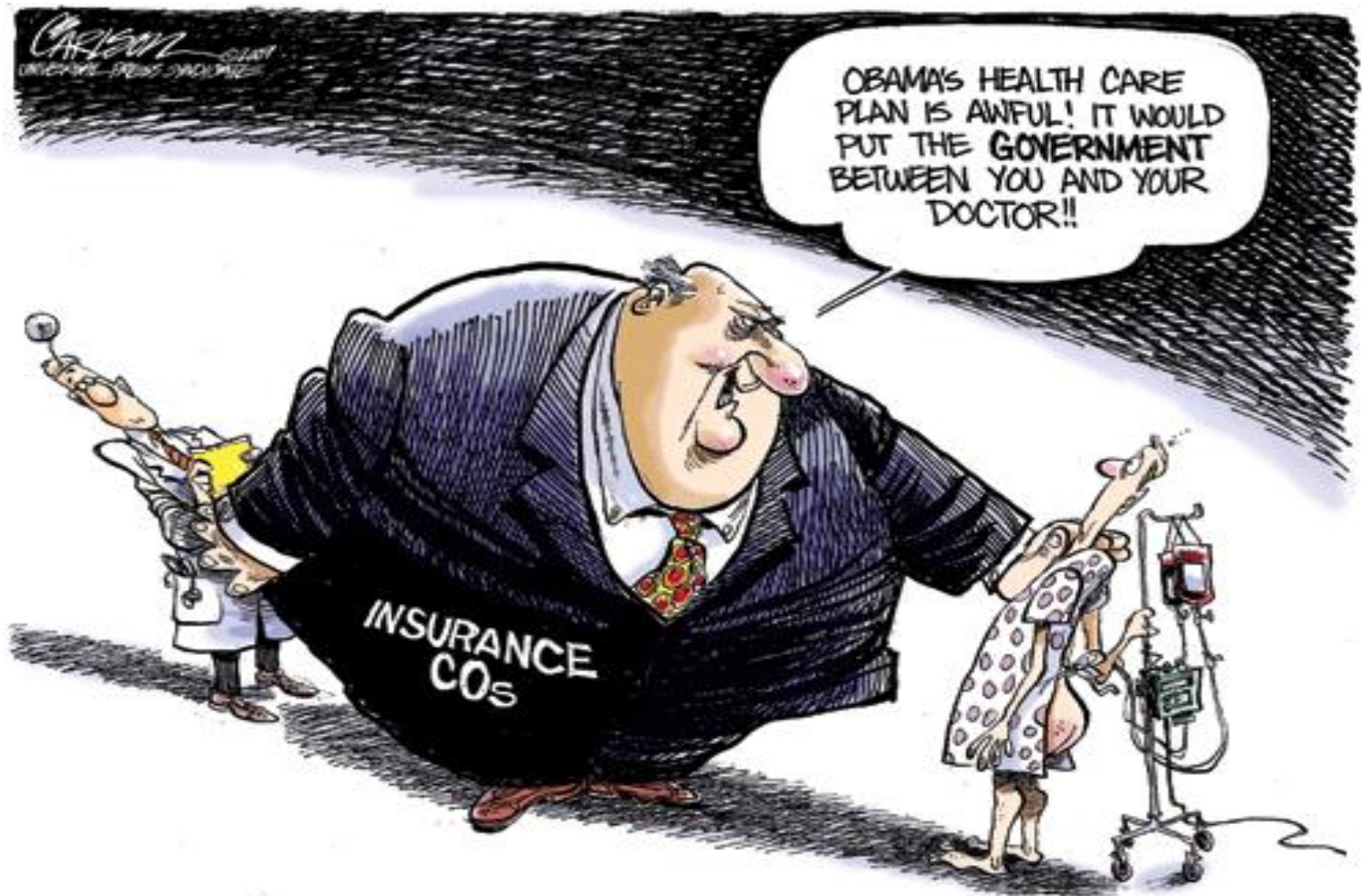
3. How do we proceed with potentially lifesaving technology? (with bad early results)

National Organ Transplant Act 42 USCS, 273 *et seq.*(1984)

- Passed as response to continuing shortage of organs
- Creates Organ Procurement and Transplantation Network (OPTN)
- Establishes system for matching donor organs with potential patients in need and developing policies for equitable allocation of organs
- Supervised by Dept of Health and Human Services

The Federal Government's Role in Transplantation





6/24

OBAMA'S HEALTH CARE PLAN IS AWFUL! IT WOULD PUT THE GOVERNMENT BETWEEN YOU AND YOUR DOCTOR !!!

United Network for Organ Sharing (UNOS)

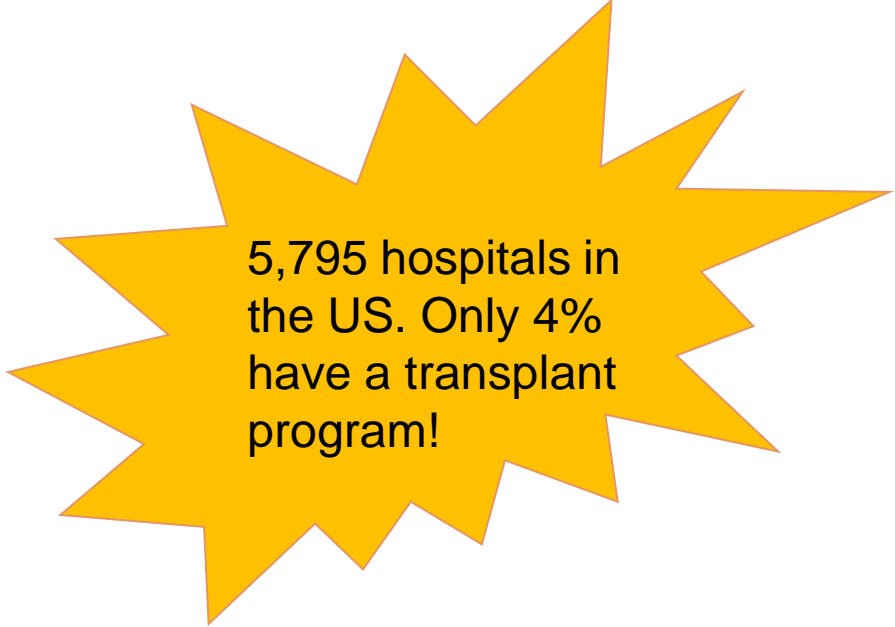
- Originated from South Eastern Organ Procurement Foundation (SEOPF) in 1986
- Sole bid for OPTN contract in 1987
- Direct reporting /oversight from HRSA/HHS
- 300+ employees
- As a contractor, UNOS has specific “deliverables” as part of it’s responsibilities



UNOS Membership

- 248 Transplant Centers

- Kidney - 238
- Liver – 134 (72 Living)
- Heart - 132
- Heart/Lung - 50
- Intestine - 43
- Lung - 66
- Pancreas Islet Cell - 23
- Pancreas – 143



5,795 hospitals in the US. Only 4% have a transplant program!

- 58 Organ Procurement Organizations (OPOs)

- 158 Histocompatibility Labs

- Other Organizations

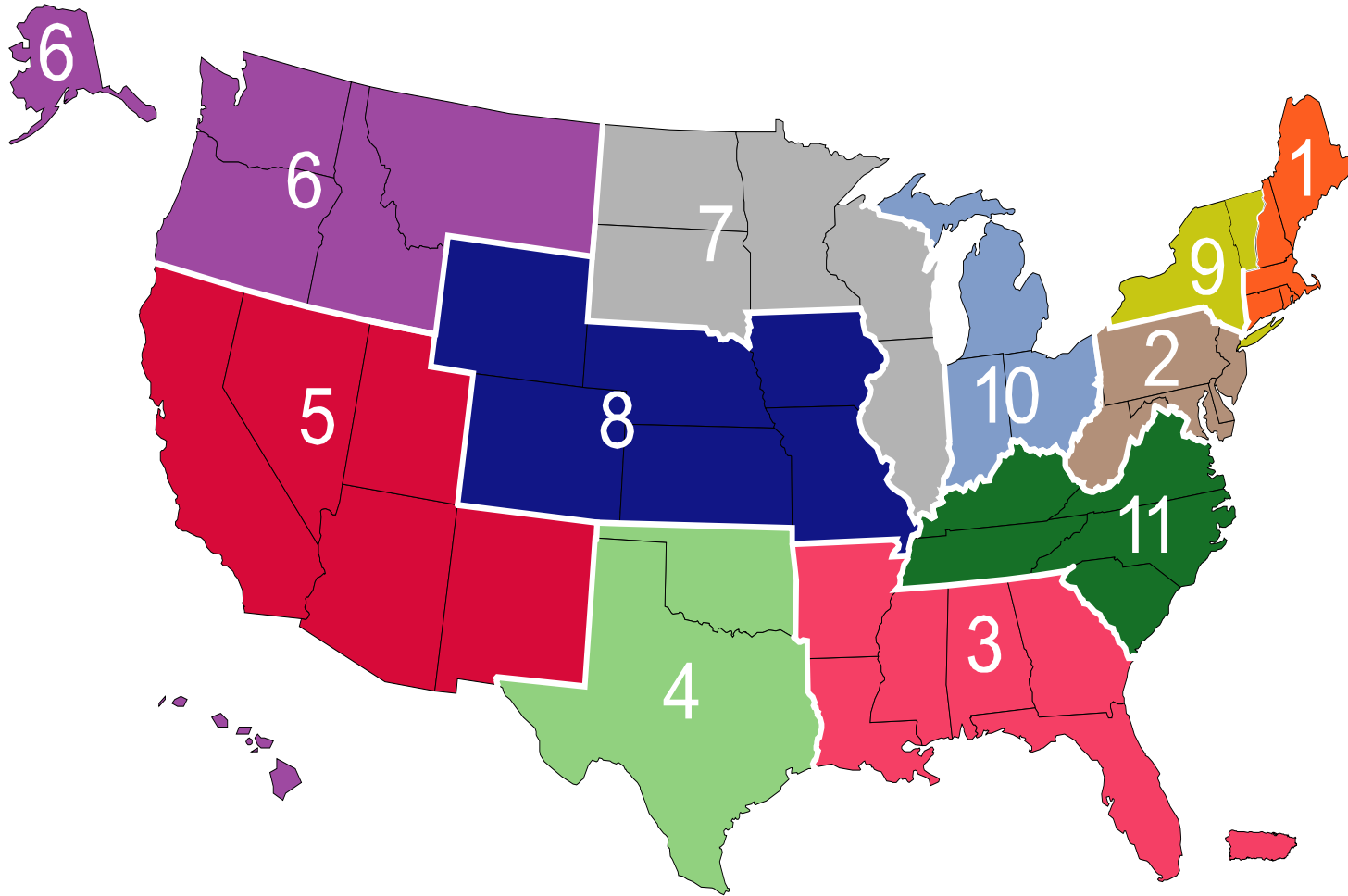
The OPTN as a Component of the American Health Care System

- OPTN one of many components
- State boards of medicine – licensure and discipline of individuals
 - OPTN has no authority over individual practitioners
- State health departments – licensure & inspection of facilities
 - OPTN has no authority to limit the number of centers
- HRSA requirements in Final Rule for centers and OPOs
- CMS conditions of participation for centers and OPOs
- Joint Commission
- State coroners and prosecutors; US Justice – criminal behavior
- State courts and malpractice claims

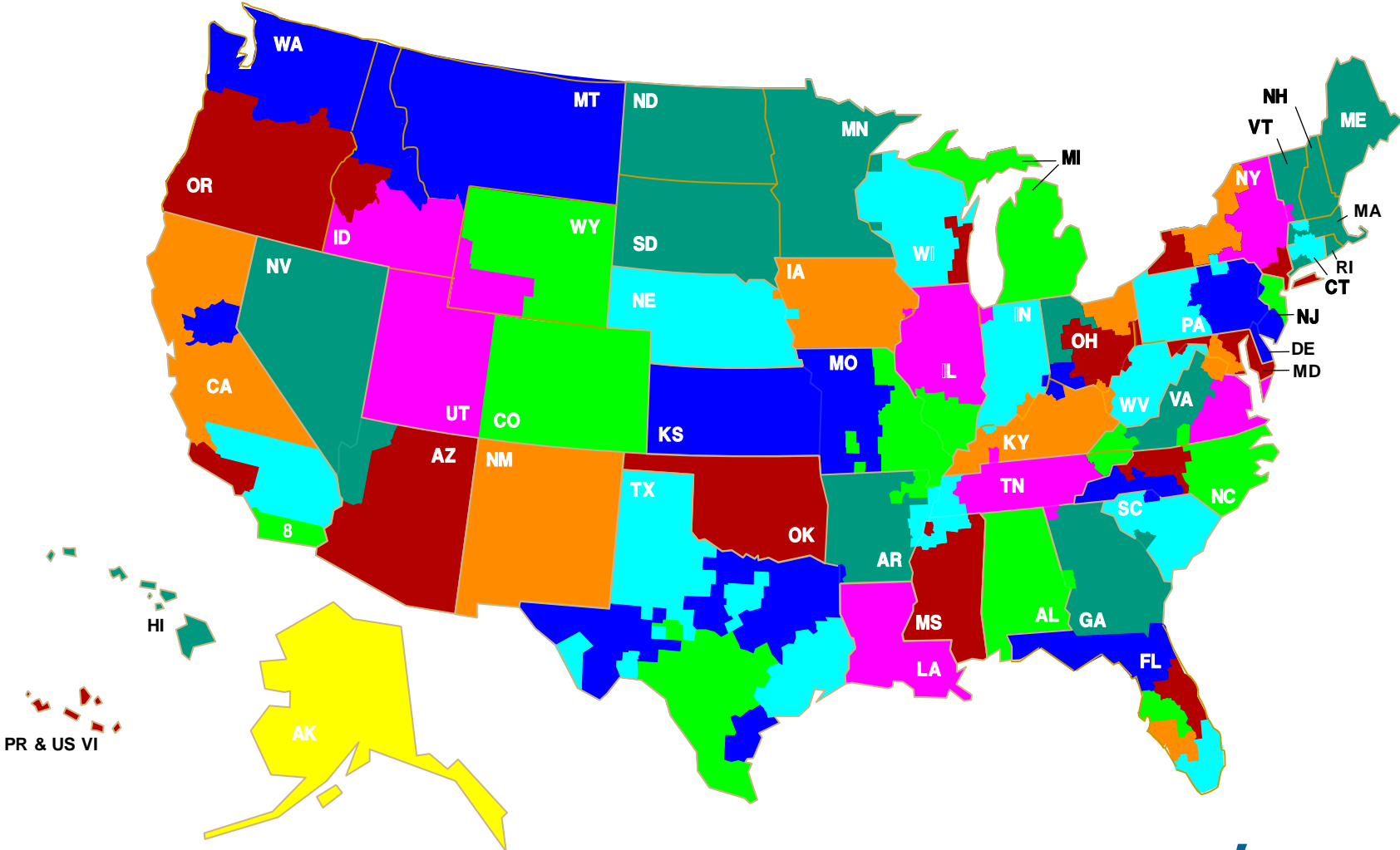
OPTN Scope

- All patients awaiting **organ** transplant: kidneys, liver, heart, lungs, pancreas, intestine
- All living and deceased **organ** donors
- All deceased **organ** donor/candidate matches
- All **organ** transplants
- All OPOs
- All transplant centers

UNOS Regional Map



OPO Service Areas



UNOS-Organ Center



The Problem



Difficult decisions about Extending the Donor Pool



A balance:

**The risks of
death on the
waiting list**

versus

**The risks of
surgical
complications
or primary graft
dysfunction**

Goal of Every Transplant Program

Optimal Timing of Transplantation with the most suitable organ leading to good quality of life with event free survival

Reality of Transplant Today

Many patients die on the waiting list while the ideal donor is rare

Informed consent of every possible donor related risk factor is a CMS mandate

60 Lives, 30 Kidneys, All Linked

The New York Times

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SUNDAY, FEBRUARY 19, 2012

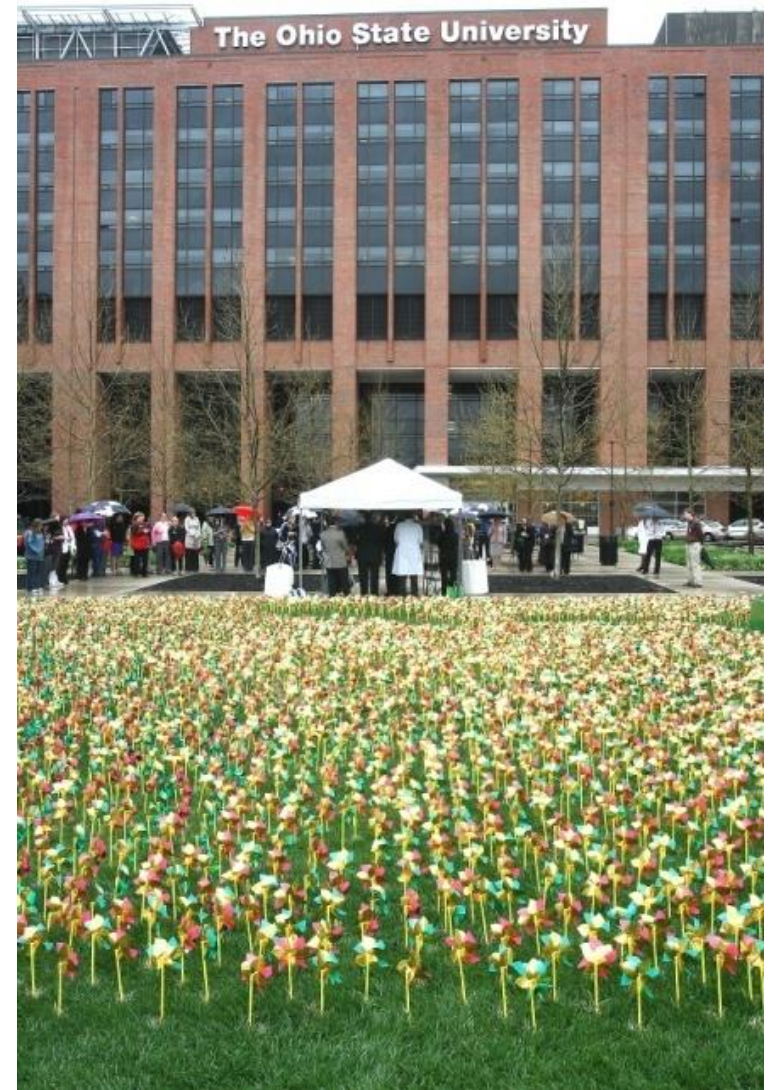


FROM START TO FINISH

A donation by a Good Samaritan, Rick Ruzzamenti, upper left, set in motion a 60-person chain of transplants that ended with a kidney for Donald C. Terry Jr., bottom right.

60 Lives, 30 Kidneys, All Linked

Intricate Balancing Act Produces a Record Chain of Transplants



Donor family member (left) and transplant recipient (right).

Transplant Program Requirements

- Surgeon (+/- fellowship)
- Physician
- RN Coordinator
- Financial Consultant
- Social Worker/Mental Health
- OPO Affiliation/support
- Histocompatibility Lab
- Operating room anesthesia/nursing
- ICU Critical care/nursing
- Pharmacy
- Blood bank
- Infectious disease

Compliance and Continuity of Care in Transplantation...

Why is it important?

- Preoperative condition of patient on waitlist impacts outcomes
- Outcomes are tracked by federal regulatory agencies and CMS
- These agencies have expectations at 1 and 3 years for survival which is reflective of follow-up care
- Lapses in perioperative and follow-up care may have significant financial impact on hospital and professional reimbursement

Transplant Care Coordination Model

- Pre Transplant period
- Waitlist period
- Transplant admission
- Post Transplant period

Quality Committees

- Each organ group has a designated quality committee.
- Each committee does routine monitoring of key elements of care utilized in the inpatient setting that are important in the transition of care to the post transplant/ambulatory care setting (Hemoglobin at the time of d/c, Creatine at the time of d/c).
- Results of this monitoring are shared on a quarterly basis as part of the monthly quality committee activities. Committee members discuss results of these monitoring activities, identify any trends/issue if applicable, perform root cause analysis for any issues identified and develop/implement solutions to address problems identified.
- The quality committees are multidisciplinary. Membership includes:

Transplant Physician	Transplant Administration
Transplant Surgeon	Transplant Nurse Manager
Quality Representative	Pre Transplant Coordinator
Post Transplant Coordinator	Transplant Pharmacy
Transplant Infectious Disease	

UNOS/OPTN Membership and Professional Standards Committee

Transplant Outcomes

- Membership and Professional Standards Committee (MPSC) associated Data Subcommittee (DSC) conducts routine reviews of all transplant program performance by monitoring program **outcomes and activity**
- DSC meets four times a year, prior to each MPSC meeting
- Scientific Registry of Transplant Recipients (SRTR), works in partnership with the MSPC and its Data Subcommittee
- DSC utilizes the SRTR statistical model for programs that **perform ten or more transplants, over a contiguous 2.5 year period** (referred to as Large Volume Programs).

MPSC Composition

- 12 Surgeons
- 10 Physicians
- 4 OPO Representatives
- 1 Transplant Administrator
- 1 Lab Director
- 1 Transplant Coordinator
- 2 Transplant Recipients

Post transplant Outcomes

Organ	1 year patient survival	1 year graft survival	5 year patient survival	5 year graft survival
Liver-deceased donor	86.9%	82.4%	73.4%	67.4%
Liver-living donor	91.2%	84%	76.8%	68.8%
Kidney-deceased donor	94.7%	89.5%	80.7%	67.1%
Kidney-living donor	98%	95.1%	90.4%	80.3%
Kidney-pancreas	95.1%	85.2%	85.8%	71.1%

Transplant Review Process

MPSC/DSC Review Process

- Once a program is identified for review, the program is sent a survey. This survey requests a validation of the data submitted into Unet system
- A synopsis of the deaths and/or graft failures that occurred within one year of transplant is also requested for review. The DSC considers changes in key personnel, changes to processes and procedures within the transplant program
- Potential recommendations for programs under review :
Release from reporting, Continue to report , Peer Visit , Informal Discussion

OPTN Compliance Process

Unifying Themes

- Member organizations, programs , OPO's and practioners encouraged to fully understand and voluntarily comply with bylaws, policies and procedures of OPTN
- Membership and Professional Standards Committee provides specific oversight for non-adverse actions and reports adverse actions to Board of Directors, HRSA, HHS
- ***Ultimate goal is to enhance clinical care, patient safety and process improvement through peer-review and consensus development***

Role of CMS



University of Toledo Medical Center personnel explain operating procedure for kidney transplants. *THE BLADE/DAVE ZAPOTOSKY* [Enlarge](#)

Changes in place after botched surgery

Failed kidney transplant at UTMC prompts new safeguards

BY JENNIFER FEEHAN
BLADE STAFF WRITER

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Lead surgical nurse Sara King placed a small metal bowl into the icy slush that sat just a few feet from the operating table inside Operating Room 5 at the University of Toledo Medical Center.

Ed Hall promptly replaced the metal basin with a square plastic box marked "donor kidney," explaining that this is the new container to be used for organs awaiting transplant.

"Simple is good," said Mr. Hall, administrator of surgical services for UTMC, the former Medical College of Ohio.

PHOTO GALLERY: UTMC kidney transplant tour

The new container, which has both a lid and a label, is a small but significant change in the way UTMC surgical teams are to perform kidney transplants in the aftermath of an Aug. 10 surgery in which a viable kidney was removed from a young man, cleaned, placed in a metal basin, stored in the slush machine to await transplant, and then inadvertently thrown away by a nurse who apparently was unaware the organ was in the slush.

Although the mistake was quickly discovered, it took nearly two hours for the kidney to be retrieved from the hospital's medical waste system, and it could not be safely implanted into the waiting patient, the donor's sister.



A lid for a donor kidney used during a kidney transplant.

The mistake — deemed "baffling" by a medical reviewer and "an inexplicable human error" by UT President Dr. Lloyd Jacobs — has prompted a complete review of policies and procedures in the surgery department at UTMC and at hospitals across the country where organ transplants are performed. UTMC's living-donor kidney transplant program remains on voluntary suspension.

"We know what happened. Why it happened is baffling, and that's the human error element of it, which we've been unable to explain," Mr. Hall said during a tour of the operating room where the incident occurred. "Why does anyone make a mistake at any point in the day? Distraction? Having a bad day?"

"What we try to do here, regardless of this incident, is to put processes in place to reduce the risk of human error, and unfortunately we had this terrible incident," he said. "We're taking it very seriously. We looked at everything we do with a fine-toothed comb. We changed some of the things we do."

Among the new policies and the changes:

- Nothing may leave the operating room until the patient has been removed after surgery.

- Members of the surgical team must check with the surgeon before going on break.
- An infrared motion detector has been mounted near the slush machine that sounds an alarm when anyone gets close to it.
- A ring-shaped magnetic device has been designed to fit on top of the slush machine. It will have a visual and auditory alarm that will go off when it is lifted.

"Mistakes spur innovation and improvement, and I think they have begun to do that already," Dr. Jacobs told *The Blade* last week. Mr. Hall, who was temporarily placed on paid leave after the incident and then was reinstated, said no one in the transplant community had heard of a viable organ being discarded before it happened at UTMC.

"This exact incident isn't on anybody's radar screen in the country — lots of other issues are — so nobody was walking around saying, 'How can we prevent this exact type of incident?'" Mr. Hall said. "This showed us that it could happen."

Checks and balances

Still, Dr. Robert Higgins, director of the comprehensive transplant center at Ohio State University Wexner Medical Center and a former president of the United Network for Organ Sharing, said there is a reason this kind of aberration has not occurred before.

"The fact that this hasn't happened anywhere else is probably because there are already checks and balances in place," he said, explaining that OSU requires that donor organs be packaged and labeled after removal and that they not leave the sight or control of the operating surgeon.

Still, Dr. Higgins said the entire transplant community is following what happened in Toledo, and his own medical center has taken a look at its policies in light of the incident.

"We've reinforced our senses to what we should be doing and how we should be conducting our affairs," Dr. Higgins said.

UTMC said that is a constant process — mistake or no.

Role of CMS

All currently approved transplant centers that continue to participate in Medicare, are required to submit a request for initial approval. Once approved by Medicare, transplant centers are eligible for re-approval every 3 years.



CMS Conditions of Participation (COPs)

- **Standard: Data submission (CTC-007)**
 - No later than 90 days after the due date established by the OPTN, a transplant center must submit to the OPTN at least 95 percent of required data on all transplants
- **Standard: Clinical experience (CTC-007)**
 - Annual volume for the following types of transplant centers is required:
 - Heart, kidney, liver & lung transplant centers – 10 transplants
 - No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants
- **Standard: Outcome measures (CTC-007)**
 - ***A center's (risk-adjusted) expected 1-year patient survival and 1-year graft survival will be compared to its observed 1-year patient survival and 1-year graft survival, based on the following non-compliance thresholds:***
 - $O - E > 3$
 - $O/E > 1.5$
 - $1\text{-sided } p < 0.05$

CMS Conditions of Participation

Clinical Experience

- Annual volumes requirements for the following types of transplant centers:
- Heart, intestine, kidney, liver & lung transplant centers = 10 transplants
- No annual volume requirement for heart-lung, and pancreas centers, and centers that primarily perform pediatric transplants.

CMS Conditions of Participation

Patient and Living Donor Selection

Patient selection criteria must:

- Assure fair and nondiscriminatory distribution of organs
- Include a psychosocial evaluation
- Include documentation in the patient's medical record that the candidate's blood type has been determined on at least two separate occasions
- Include documentation in the patient's medical record of the patient selection criteria used
- Selection criteria must be available upon request

Living donor selection

- The living donor selection criteria must be consistent with the general principles of medical ethics.

Transplant centers must:

- Ensure that a prospective living donor receives a medical & psychosocial evaluation prior to donation
- Document in the living donor's medical records the living donor's suitability for donation
- Document that the living donor has given informed consent, as required.

Case in Point

- You are recruited to established academic transplant program
- Past observed outcomes in kidney (N=50) are not meeting expected outcomes (5 graft losses, 4 deaths from MI, PE, head trauma and infection)
- Quality improvement process has addressed patient care issues but outcomes still not meeting expectations
- OPTN/CMS “flag” your program 2 consecutive cycles
- CMS contacts program director requesting explanation
- Your team submits rationale explanations saying transplant (like life) isn't perfect!



"Hi, I'm here about the Arena Events job listing?"

Process For Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers

A. Background

Under the authority of 42 CFR §488.61 (a)(4), (b)(2) and (c)(4), a transplant program may request that the Centers for Medicare & Medicaid Services (CMS) consider mitigating factors in the initial approval and re-approval of a transplant program that does not meet one or more Conditions of Participation.

The regulation describes three general areas that will be reviewed in determining whether or not a program can be approved based on mitigating factors. These areas include (but are not limited to): 1) the extent to which outcome measures are met or exceeded; 2) the availability of Medicare-approved transplant centers in the area; and 3) extenuating circumstances that may have a temporary effect on meeting the Conditions of Participation.

In most cases CMS will schedule a conference call with the hospital to discuss the results of the CMS review about 30 days after CMS' receipt of the completed request for consideration of mitigating factors.

Process For Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers

B. Requesting Approval Based on Mitigating Factors

A transplant program seeking approval based on the presence of mitigating factors should:

- 1) Submit a formal written request for approval to the CMS Central Office contact and address specified below **within 10 calendar days from the notification date on the letter accompanying the CMS-2567 form** (this form outlines survey results) in order to get timely attention before any possible enforcement action is taken on the cited deficiencies.
- 2) Submit any final (additional) explanatory materials **within 30 calendar days following the date of the notice accompanying the CMS-2567 form.**

CMS Regulatory IMPACT

- Program Actual outcomes below Expected outcomes
 - Based on SRTR data cohort from 1/1/09-6/30/2011
 - 2 times in the past 30 months with one of two times being most recent cohort
 - **Next report to be published January 2014 (7/1/10-12/31/12)**
- Systems Improvement Agreement
 - Facilitate quality system improvements that will enhance the existing program
 - Enter into agreement (hospital pays for ALL activities)
 - 12 month agreement
- Independent Peer Review
 - Panel of transplant professionals (surgeon, physician, SW, Txp. Admin, RN, QA)
 - Provide recommendations that become the Quality Action Plan
- Ongoing Consultant guidance
 - 6 days/month on site for EACH program
 - Assist with execution of Quality Action Plan
 - Connectivity back to CMS re: program's progress

CMS SIA Update

General Themes:

- Multi disciplinary rounding ... daily
- Transition post operative care during inpatient admission from Surgery to Medicine after patient moved out of ICU care
- Improve Medical and Surgical collaboration
- Social Work, Dietary, Pharmacy involved across entire care continuum
- Electronic medical record development
- Root Cause Analysis (RCA) on every death and graft loss
- PSC to be multidisciplinary with all disciplines present and voicing their opinions. Needs to go GREEN with real time documentation.
- Surgeons/Physicians involved with UNET data collection

Keys to Success in The Current clinical and regulatory environment

- Understand the OPTN,CMS requirements
- Develop a strong, prospective administrative understanding and or role
- Accurate data submission is critical to appropriate risk adjustment
- Quality Assessment and Process Improvement (QAPI) program- fix problems in real time
- ***Do Good work*** -there is no replacement for good patient selection, appropriate donor management and selection, outstanding surgical/medical expertise and comprehensive follow-up

Transplant Signature Program

Teamwork committed to Quality and Quantity of Life –
OSUMC 2010

