HELEN G SPICER, RN

PAST PRESIDENT

AMERICAN FOUNDATION FOR DONATION AND TRANSPLANTATION

OBJECTIVES

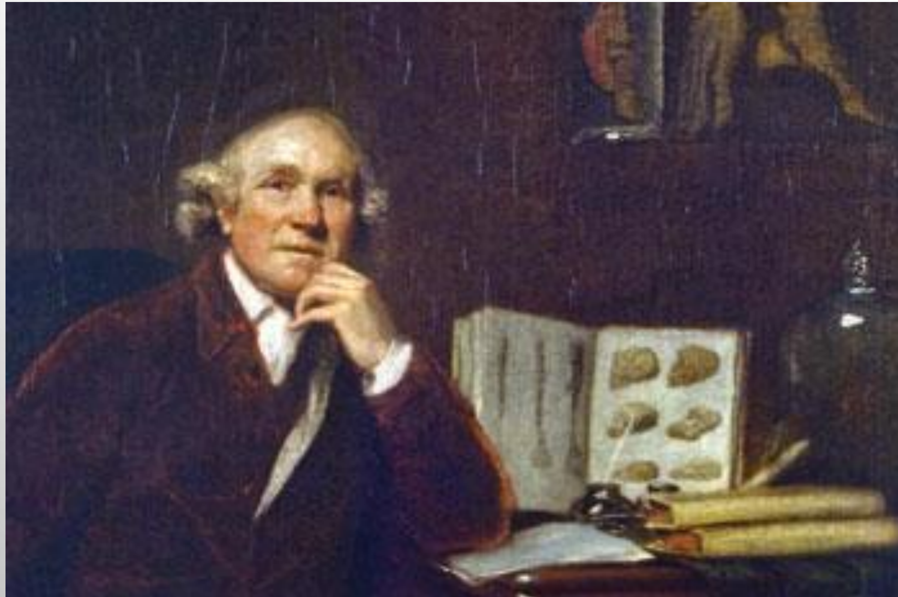
- THE PROFESSIONAL DELIBERATIONS THAT INFORMED THE DECISION TO PROCEED WITH LIVING DONATION AS AN OPTION FOR KIDNEY TRANSPLANTATION.
- KEY ADVANCEMENTS AND THE IMPACT ON LIVING DONATION

DISCLOSURES

I HAVE NOTHING TO DISCLOSE

JOHN HUNTER 1728-1793

John Hunter
Founder of an approach to surgery based on observation and experiment.



THE KNIFE MAN – Wendy Moore

TOOTH TRANSPLANTS

- NOTED THAT TISSUES HAD TO BE GRAFTED QUICKLY AFTER REMOVAL OTHER WISE THE "LIFE PRINCIPLE" IN THE GRAFT WOULD BE LOST.
- NOTED THAT DISEASE COULD BE TRANSFERRED

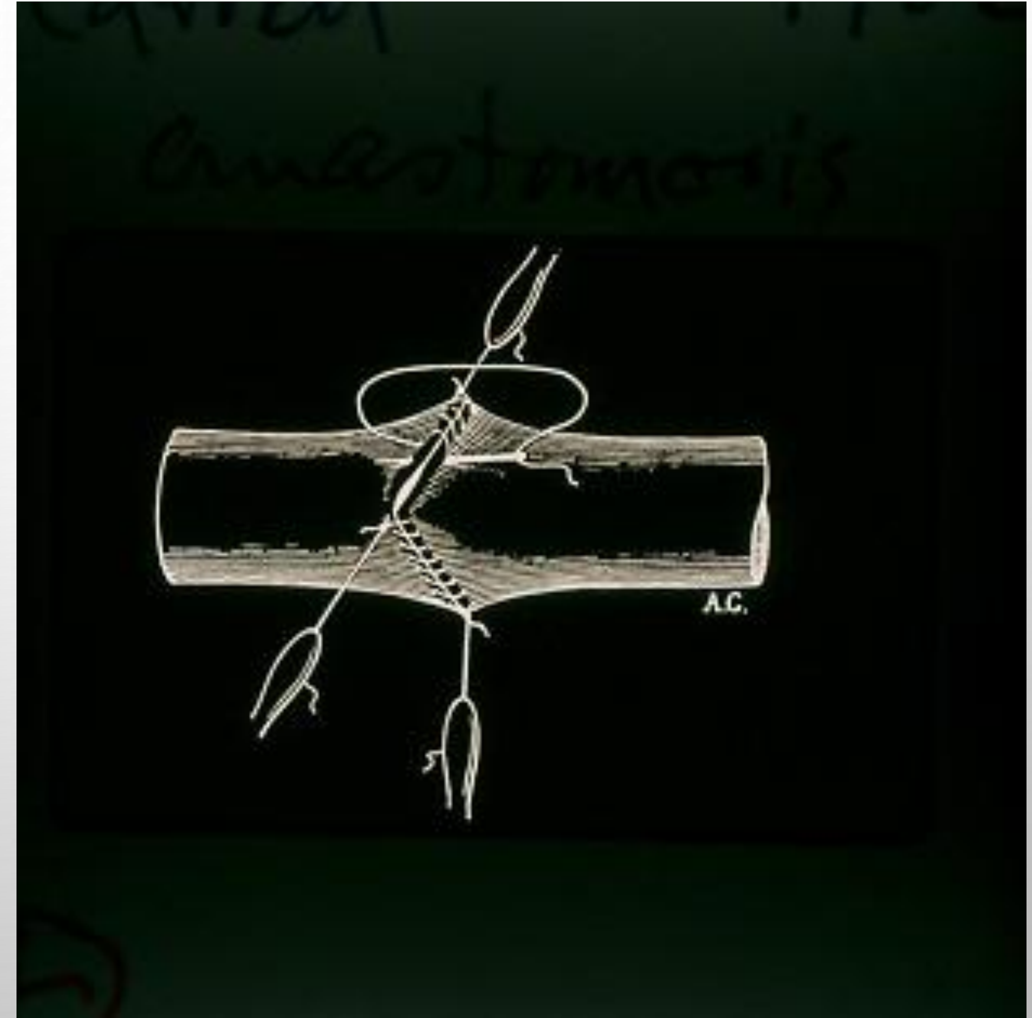
- **ETHICAL ISSUES RAISED**
  - **SERVANTS OR SOLDIERS WERE BEING COERCED INTO DONATING TEETH TO THEIR MASTERS. MAY RECEIVE PAYMENT.**
  - **IS THIS PRACTICE A DEFECT IN MORAL PRINCIPLE ?**

ALEXIS CARREL 1902

- HE HAD AN INDEPENDENT MIND AND PUNGENT PERSONALITY.
- HE DID NOT ACCEPT TRADITIONAL DOGMA.
- CAME TO AMERICA THROUGH CANADA
- HIS LAB ASSISTANT CHARLES LINDBERG
- .

ALEXIS CARREL
1902

- 1902 PUBLISHED HIS TECHNIQUE OF BLOOD VESSEL ANASTOMOSIS.
- BORN IN LYON FAMOUS FOR FINE LINEN, TO MERCHANT FAMILY.
- HE WAS TAUGHT TO USE FINE NEEDLES AND FINE THREAD TO SEW BY MOTHER'S SEWING CIRCLE.

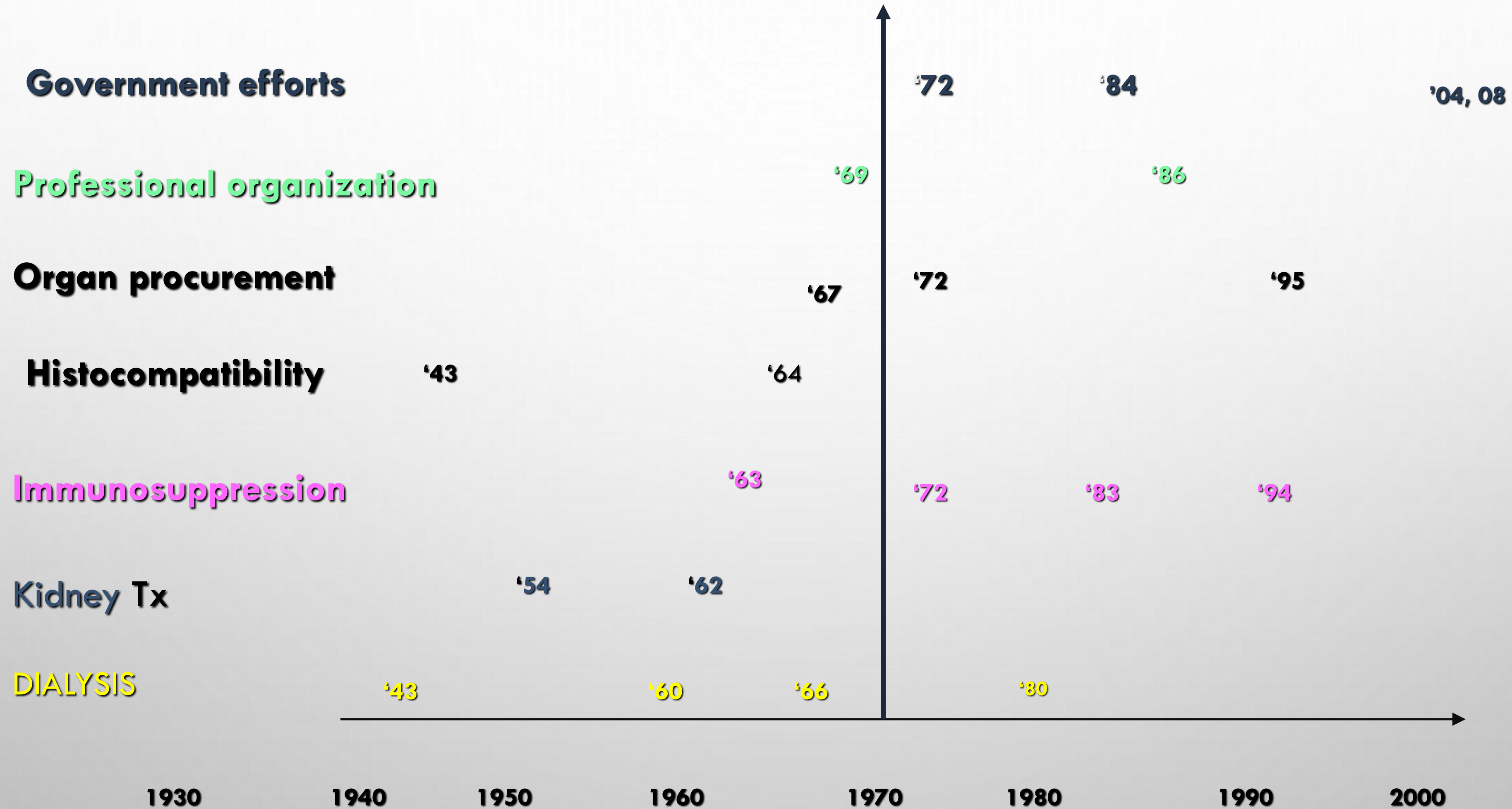


WHAT ARE THE BARRIERS TO TRANSPLANT?

IS IT POSSIBLE FOR ORGAN TO BE REPLACED?

- IF SO:
  - HOW TO ATTACH BLOOD VESSELS?
  - HOW TO OBTAIN KIDNEYS – LIVING DONORS AND DECEASED DONORS?
  - HOW TO PRESERVE THEM UNTIL THEY CAN BE USED?
  - HOW TO KEEP THEM FROM REJECTING?
  - HOW TO KEEP SOMEONE ALIVE UNTIL A KIDNEY CAN BE FOUND?
  - HOW TO PAY FOR ALL OF THIS?
  - HOW TO HAVE THE SERVICE FOR ALL WHO NEED IT?

BRIEF HISTORY OF DIALYSIS & TRANSPLANT



SIR PETER MEDAWAR

- THE FATE OF SKIN HOMOGRAFTS IN MAN J. ANATOMY, LONDON 77:299, 1943
- IMMUNOLOGICAL BASIS FOR THE REJECTION WAS ESTABLISHED.
  - FIRST SET AND SECOND SET REACTION

NOBEL PRIZE 1960

1950-1970
THE EXPERIMENT YEARS

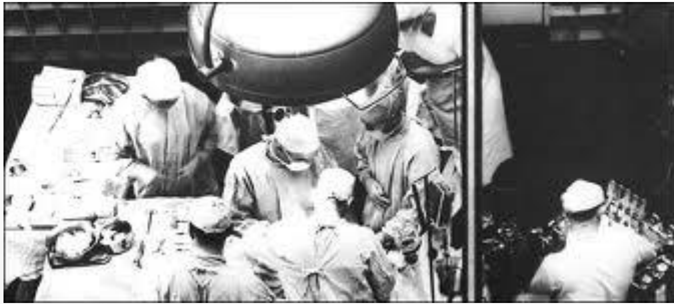
- KIDNEY TRANSPLANT:
  - IDENTICAL TWIN 1954
  - DECEASED DONOR 1962
- IMMUNOSUPPRESSION: PREDNISONE/IMURAN 1963; RADIATION SELECTIVELY.
- **HISTOCOMPATIBILITY:** 1964 PAUL TERASAKI DR. AMOS
- **ORGAN PROCUREMENT**: 1967 DR. BELZER HAD DESIGNED A KIDNEY PERFUSION MACHINE & PRESERVATION SOLUTION.
- **SOUTH EASTERN REGIONAL ORGAN SHARING**: 8 TRANSPLANT CENTER SHARING NETWORK: 1969

- DIALYSIS
  - HEMODIALYSIS 1960
  - PERITONEAL DIALYSIS IS FOR ACUTE TREATMENT.
- VASCULAR ACCESS
  - EXTERNAL SHUNTS: 1960
    - SCRIBNER
  - INTERNAL AV FISTULA:1966
    - CIMINO

IDENTICAL TWIN TX BOSTON 1954

- DECEMBER 23, 1954
- MURRAY, MERRILL, HARRISON

- RICHARD HERRICK 23
- RONALD HERRICK 23
  - (DONOR)



Richard married his Nurse had 2 children. 8 yrs later he died from recurrence of disease.

Ronald Married, was a school teacher
Died at age 79 after heart surgery.

Attended the Transplant Games with tee shirt that noted he was the First Living donor

JOSEPH MURRAY 1954

KIDNEY COULD BE SURGICALLY PLACED

IDENTICAL TWIN AVOIDED IMMUNOLOGICAL BARRIER

OUTLINED PLAN FOR LD REVIEW:

1. SEPARATE TEAM OF PHYSICIANS FOR LD
2. PSYCHOLOGICAL EVALUATION FOR DONOR
3. PROVIDED INFORMATION FOR LIKELY OUTCOMES FOR THE RECIPIENT

Nobel Prize 1990

THE IDENTICAL TWIN KIDNEY TRANSPLANT 1954: CONVERSATION WITH THE DONOR, RONALD

RONALD ASKED, "WILL THE HOSPITAL BE RESPONSIBLE FOR MY HEALTHCARE FOR THE REST OF MY LIFE?"

DR. HARRISON, THE SURGEON FOR THE DONOR , SAID

" OF COURSE NOT…..BUT RONALD DO YOU THINK ANYONE IN THIS ROOM WOULD EVER REFUSE TO TAKE CARE OF YOU IF YOU NEEDED HELP?"

AT THAT MOMENT RONALD UNDERSTOOD, HIS FUTURE DEPENDED UPON OUR SENSE OF PROFESSIONAL RESPONSIBILITY RATHER THAN ON LEGAL ASSURANCES.

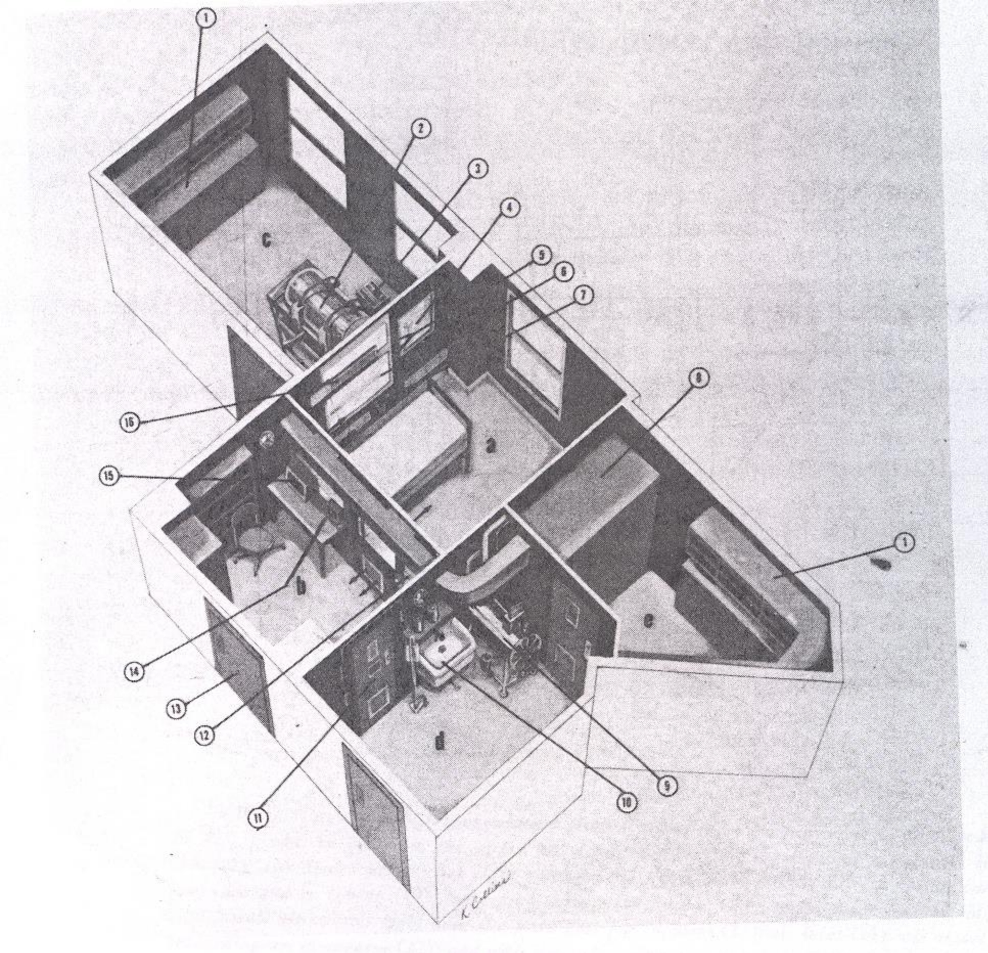
Surgery of the Soul – Joseph E Murray, M.D.

DAVID M. HUME
1955

- **EXPERIENCES WITH RENAL HOMOTRANSPLANTATION IN THE HUMAN: REPORT OF 9 CASES**
- **BY DAVID M. HUME, JOHN P. MERRILL, BENJAMIN F. MILLER, AND GEORGE THORN**
  - **DEPARTMENT OF SURGERY AND MEDICINE, HARVARD MEDICAL SCHOOL & THE PETER BENT BRIGHAM HOSPITAL, BOSTON, MASS**
  - **J. CLIN. INVEST. VOL. 34:347, FEB. 1955**

THE MEDICAL COLLEGE OF VIRGINIA (VCU)
DAVID HUME, MD

Clinical Transplant Center 1962



IMMUNOSUPPRESSION

HOW TO ALLOW THE ORGAN TO SURVIVE & NOT HAVE THE PATIENT DIE FROM INFECTION?

DRUG- IMMUNOSUPPRESSION PROTOCOL BY END OF 1960'S

- PREDNISONE
- IMURAN

- LOCAL RADIATION TO THE TRANSPLANTED KIDNEY
- ANTILYMPHOCYTE AGENT – ATG
  - SOME PROGRAMS USED INDUCTION
  - SOME DID NOT

HISTOCOMPATIBILITY

- D. Bernard Amos – Duke

- PAUL I TERASAKI - UCLA

TISSUE TYPING: 1964

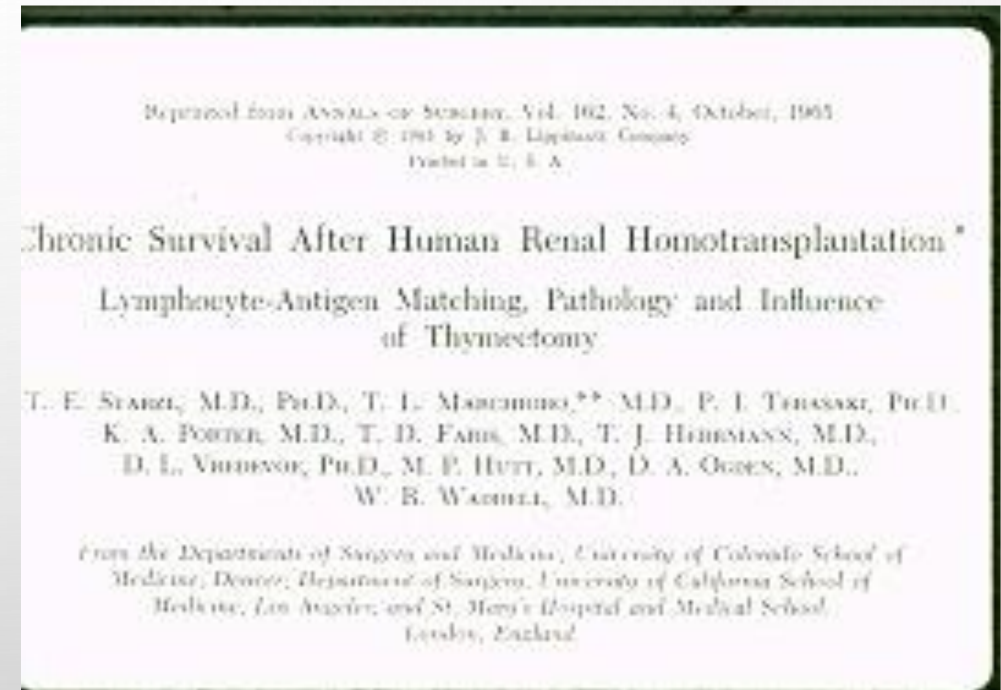
- FIRST INTERNATIONAL CONFERENCE ON HISTOCOMPATIBILITY TESTING BY AMOS OF DUKE
- TERASAKI PRESENT HIS MICRO LYMPHOCYTE CYTOTOXICITY TEST APPLIED TO KIDNEY TRANSPLANT

CHRONIC SURVIVAL AFTER HUMAN RENAL HOMOTRANSPLANTATION

<u>ANNUALS OF SURGERY</u>

1965 Terasaki and Starzle reported their experience in matching in Kidney Transplant.

Data suggested there was improvement in survival of well matched kidneys



Reprinted from Annals of Surgery, Vol. 162, No. 4, October, 1965
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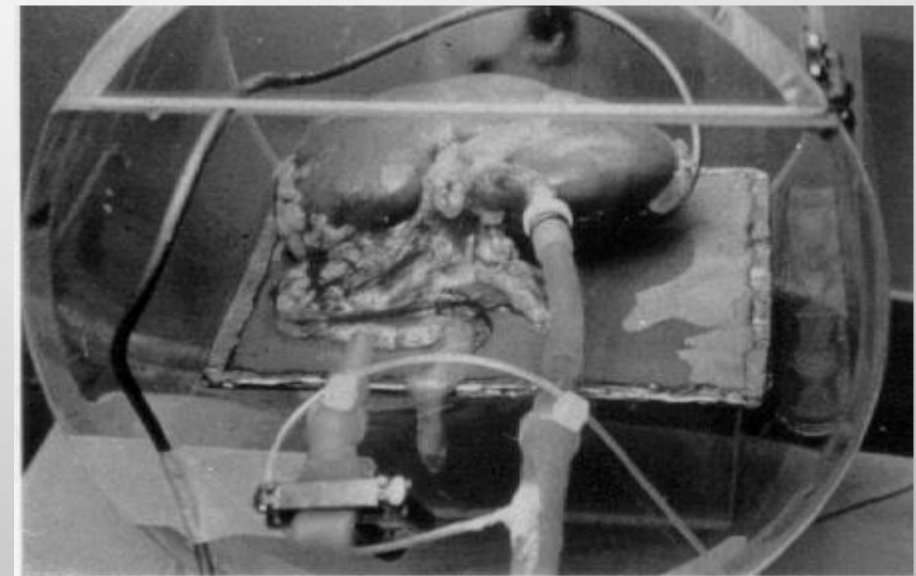
hronic Survival After Human Renal Homotransplantation *

Lymphocyte-Antigen Matching, Pathology and Influence of Thymectomy

T. E. Starzl, M.D., Ph.D., T. L. Marchioro,** M.D., P. I. Terasaki, Ph.D.,
K. A. Porter, M.D., T. D. Faris, M.D., T. J. Herrmann, M.D.,
D. L. Vredevoe, Ph.D., M. P. Hutt, M.D., D. A. Ogden, M.D.,
W. R. Waddell, M.D.

ORGAN PRESERVATION

- IN 1960 THERE WAS NO RECOGNITION OF BRAIN DEATH.
- THE KIDNEYS WERE REMOVED ONCE THE HEART STOPPED BEATING.
- THERE NEED TO BE A WAY TO PRESERVE THE ORGANS.
- 1967 DR. BELZER CREATED THE ORGAN PRESERVATION ….



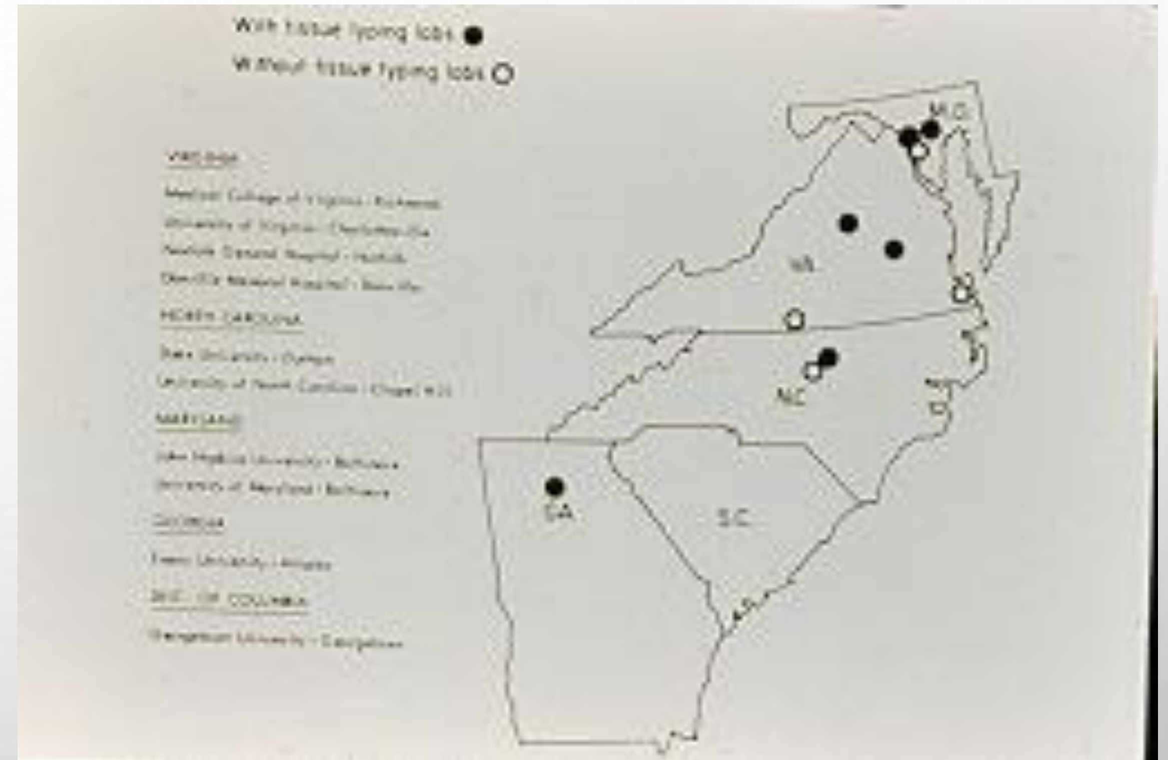
1969: SOUTH-EASTERN REGIONAL ORGAN PROCUREMENT PROGRAM (SEROPP)

DR. HUME & PROFESSOR AMOS AT DUKE FORMED A GROUP TO TEST THE UTILITY OF HISTOCOMPABILITY MATCHING.

MCV, DUKE, UNC, GEORGETOWN, JOHNS HOPKINS , UVA, UMD , EMORY

FACILITATE SHARING BETWEEN 8 HOSPITALS I 4 STATES & DC

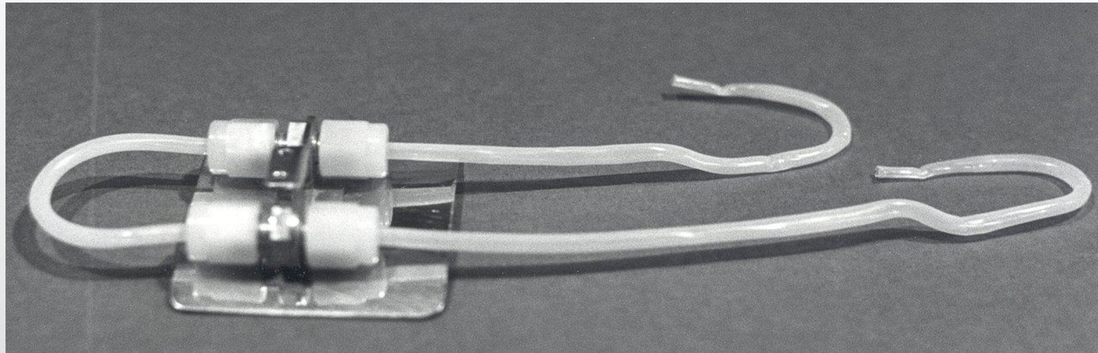
$153,000 FEDERAL GRANT TO DEVELOP AN ORGAN PROCUREMENT AND SHARING NETWORK.

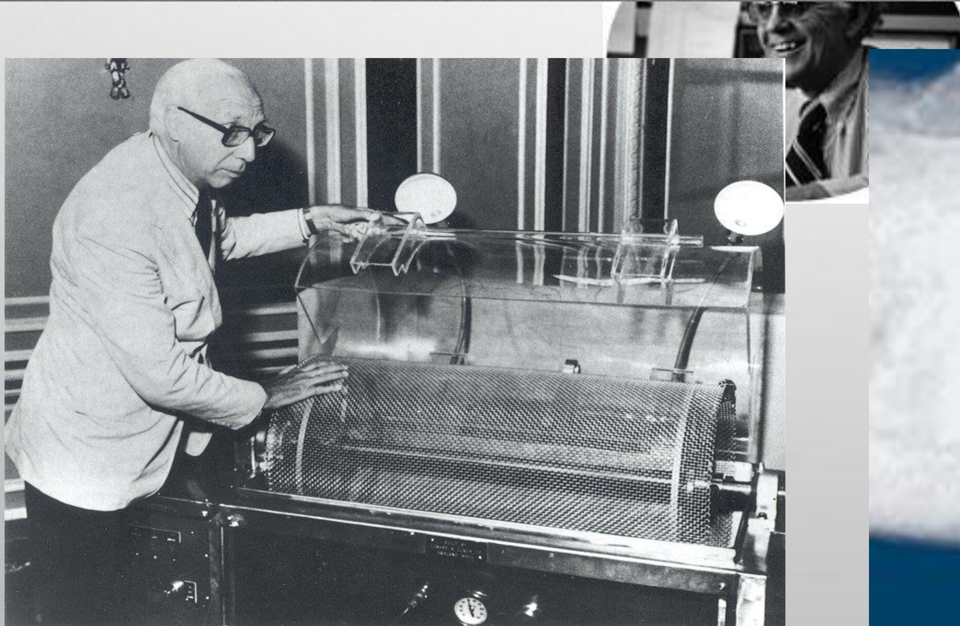


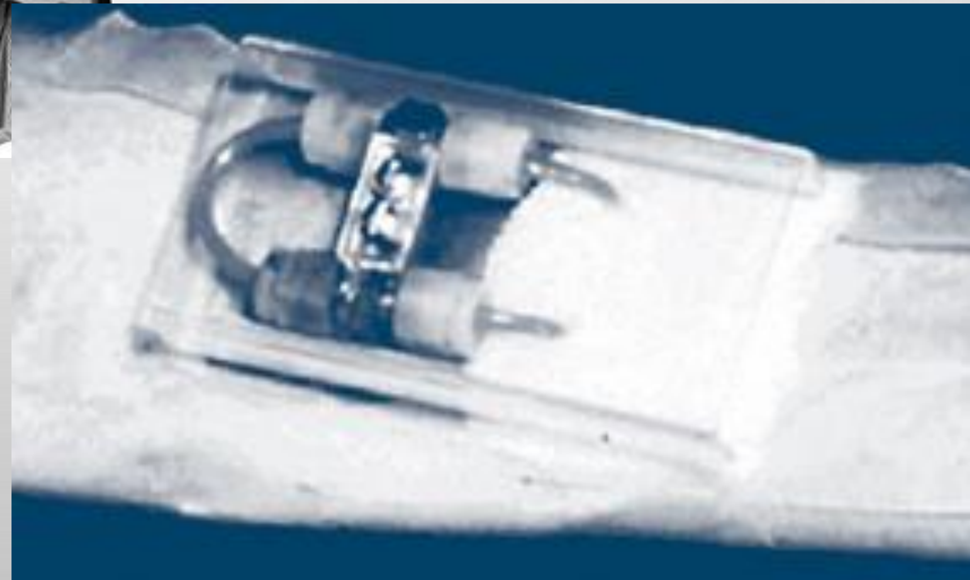
- **Orginial map of SEOPF**

THIS WAS THE BRIDGE TO
KIDNEY TRANSPLANT

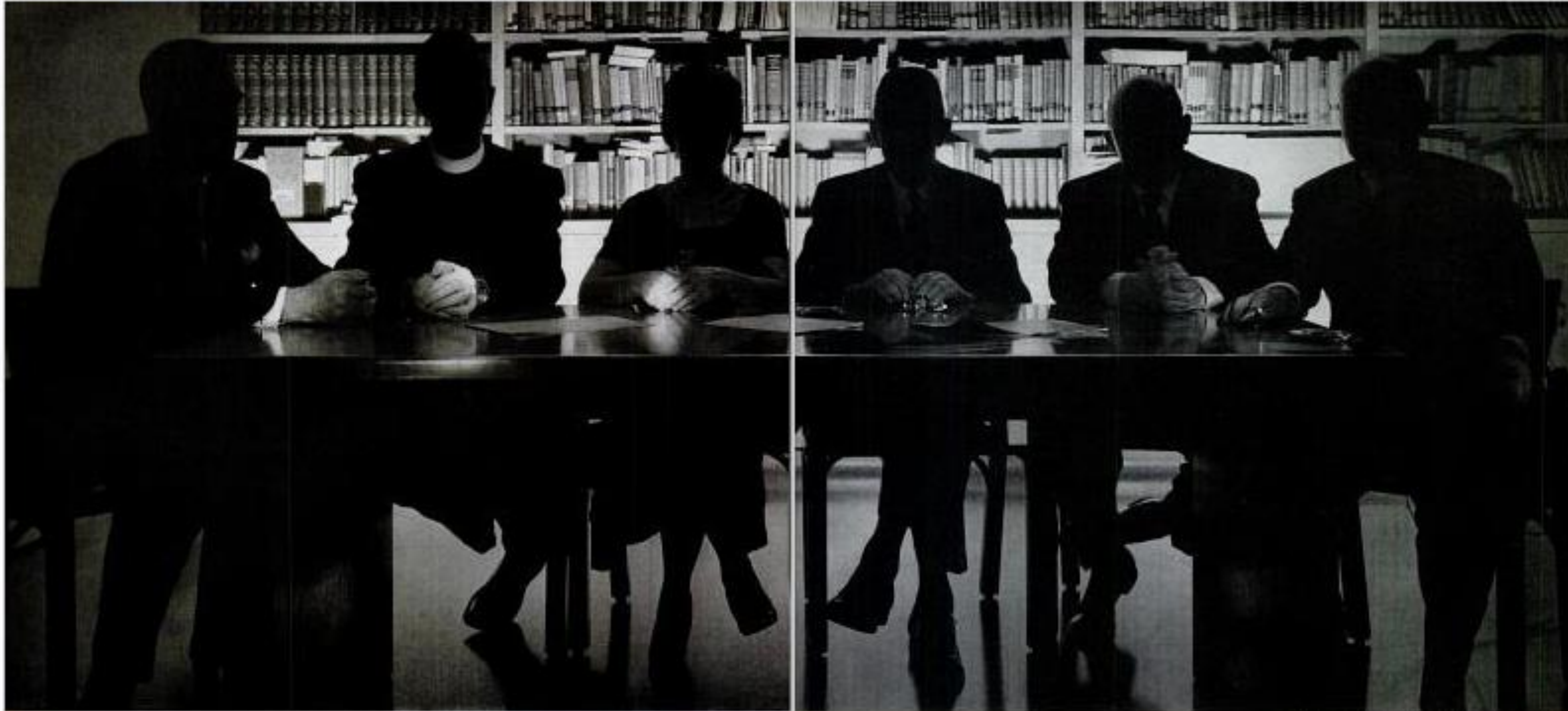
DR. BELDING SCRIBNER 1960
DIRECTOR OF THE SEATTLE DIALYSIS PROGRAM







LIFE MAGAZINE NOVEMBER 1962



Medical miracle and a moral burden of a small committee

They Decide Who Lives, Who Dies

by SHANA ALEXANDER

John Myers has known about his kidney trouble ever since a routine physical examination at the time of his Army discharge in 1945. But until two years ago he felt fine. Then the headaches began and his blood pressure began to rise. By last summer there were days when he could barely drag himself out of bed to get to his office. He was 37 years old. Neither he nor his wife Kari had any idea that he had come, irrevocably, to the terminal stage of his disease. But a glance at his case history was enough to tell any physician that John Myers' death would be ugly and soon.

Last Christmas morning when Myers awakened at his home in Bremerton, Wash. his heart was pounding violently. He could not stop coughing. Blood was running from his nose. He had an indescribable headache, a horrible taste in his mouth, dreadful nausea. His face and limbs were grossly swollen. He was rushed to a hospital where it seemed certain he would be dead within a matter of hours. But today, 11 months later, Myers is still alive. He is no longer even an invalid in the usual sense of the word. He is back at his old desk with an oil company, and he is living comfortably at home with Kari and their three young children. To the casual observer, John Myers looks and acts just like everybody else. But he is different, in a very special way. There is now a small, U-shaped plastic tube sutured into the blood vessels of his left forearm.

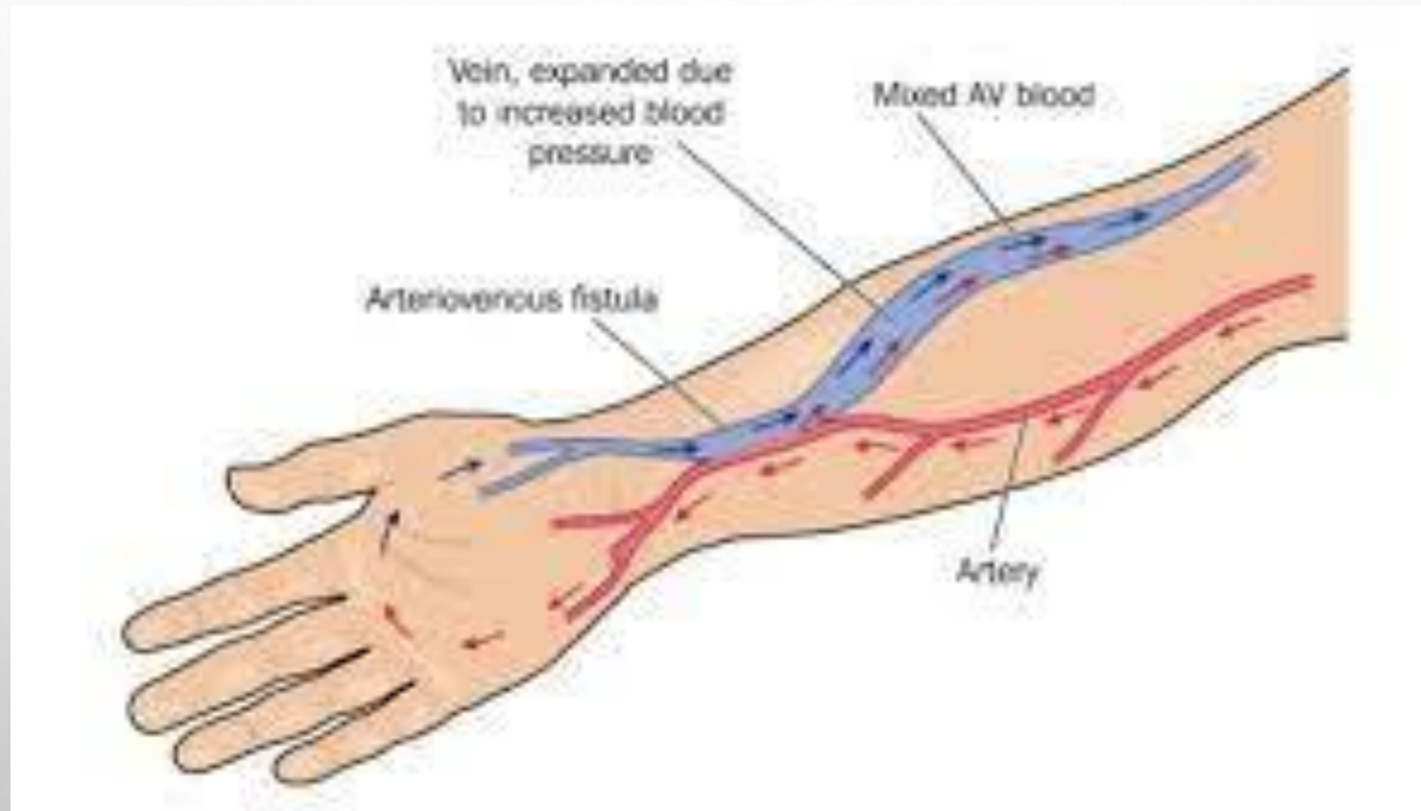
Every Monday and Thursday afternoon Myers takes an hour-long ferryboat ride across Puget Sound from Bremerton to downtown Seattle. By 6 p.m. he is making his way down a short flight of steps to an unmarked basement door in an annex of Swedish Hospital. Inside, he exchanges his business suit for a green hospital gown and climbs into bed. A compact hunk of medical plumbing which looks like a stainless steel washing machine is wheeled to Myers' bedside. From its innards a technician unfurls a pair of clear plastic tentacles six feet long. A nurse connects these to the little tube in Myers' forearm, and twiddles a few controls. Suddenly, in one bright spurt, one of the tentacles becomes red as John Myers' blood rushes out to fill the bedside machine.

The machine is an artificial kidney. Because it can be coupled at will to the U-shaped tube in Myers' forearm, it has become the first true artificial organ in medical history. For the rest of his life Myers will spend two nights a week joined by a plastic umbilical cord to this machine which keeps him alive.

At present the miraculous machine requires 10 to 12 hours to cleanse Myers' blood of accumulating poisons which otherwise would kill him. The procedure is quite painless, and Myers has now become so accustomed to the whole idea of surrendering his life's blood to a medical laundromat twice a week that during the cleansing he just goes to sleep. A

CONTINUED

1966 INTERNAL AV FISTULA DEVELOPED



THE EXPERIMENT IS OVER.

HOW TO PAY FOR ALL OF THIS?

WHERE ARE WE NOW?
DR. SCRIBNER
1970

- "IF ANYONE TOLD ME 10 YEARS AGO THAT NOW WE HAVE A WAY TO AVERT DEATH FROM KIDNEY DISEASE, THAT …WE'D BE FIGHTING OVER HOW TO PAY FOR IT, I WOULDN'T HAVE BELIEVED IT!
- WHEN YOU FIND TO ANSWER YOU ARE ½ WAY THERE . THE LOGISTICS ARE INFINITELY COMPLEX."
- WE HAVE A SHORTAGE BASED ON ECONOMICS AND LOGISTICS AND AVAILABILITY.

COURAGE TO FAIL, FOX & SWAZEY; 1974, P. 329

ORIGINS OF THE MEDICARE KIDNEY DISEASE ENTITLEMENT: THE SOCIAL SECURITY AMENDMENTS OF 1972

SHEP GLAZER MADE AN OFFICIAL STATEMENT FOR NAPH, AND THEN SPOKE ABOUT HIS PERSONAL SITUATION:

- I AM 43 YEARS OLD, MARRIED FOR 20 YEARS, WITH TWO CHILDREN AGES 14 AND 10. I WAS A SALESMAN UNTIL A COUPLE OF MONTHS AGO UNTIL IT BECAME NECESSARY FOR ME TO SUPPLEMENT MY INCOME TO PAY FOR THE DIALYSIS SUPPLIES.
- I TRIED TO SELL A NONCOMPETITIVE LINE, WAS FOUND OUT, AND WAS FIRED.
- GENTLEMEN, WHAT SHOULD I DO? END IT ALL AND DIE? SELL MY HOUSE FOR WHICH I WORKED SO HARD, AND GO ON WELFARE? SHOULD I GO INTO THE HOSPITAL UNDER MY HOSPITALIZATION POLICY, THEN I CANNOT WORK? PLEASE TELL ME. IF YOUR KIDNEYS FAILED TOMORROW, WOULDN'T YOU WANT THE OPPORTUNITY TO LIVE? WOULDN'T YOU WANT TO SEE YOUR CHILDREN GROW UP? (U.S. CONGRESS, HOUSE, COMMITTEE ON WAYS AND MEANS, 1971B

1972 HR1 MEDICARE
EXPANDED TO COVER COST OF DIALYSIS & KIDNEY TRANSPLANT

- THIS PROVIDED THE FUNDING TO EXPAND THE DIALYSIS
- PROVIDE FOR THE FUNDING OF THE ORGAN PROCUREMENT ORGANIZATION STRUCTURE
- PROVIDE FOR THE CARE OF THE KIDNEY TRANSPLANT PATIENT
- PROVIDE FUNDING FOR THE LIVING KIDNEY DONOR

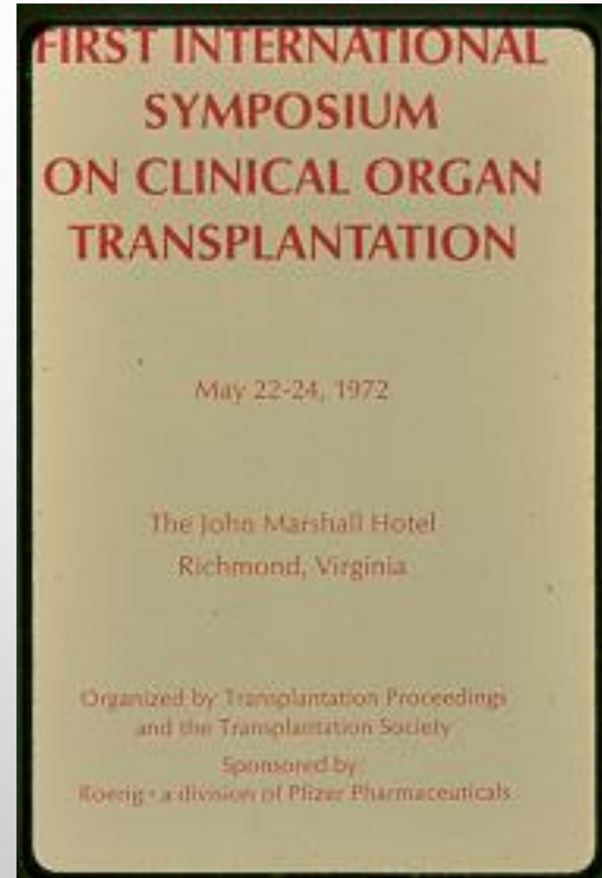
RECOGNITION OF BRAIN DEATH

- IN 1970, KANSAS BECAME THE FIRST STATE TO HAVE A CESSATION OF BRAIN FUNCTION LAW.
- 1972 - MARYLAND
- 1973 - VIRGINIA & NEW MEXICO
- 1974 - ALASKA & CALIFORNIA
- 1975 – GEORGIA, MICHIGAN & ILLINOIS

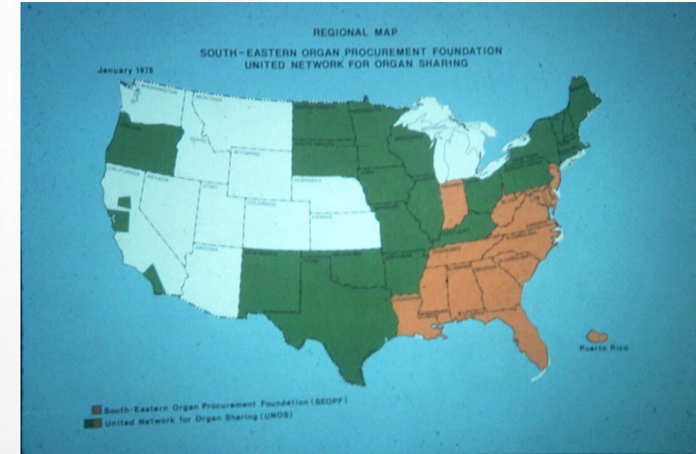
THE FIRST INTERNATIONAL CLINICAL TRANSPLANTATION SYMPOSIUM : 1972

ORGANIZED BY HUME AND RAPPORT.

- IN 20 YEARS NUMBER DONE IN USA:
  - KIDNEY 5000
  - HEART 200
  - LIVER 200
  - LUNG 40
  - PANCREAS 35



1977 SEOPF NAMED THE COMPUTER SHARING SYSTEM UNITED NETWORK FOR ORGAN SHARING (UNOS)



1969: SEOPF FOUNDED BY DAVID HUME, MD & BERNARD AMOS, PhD OF DUKE UNIVERSITY

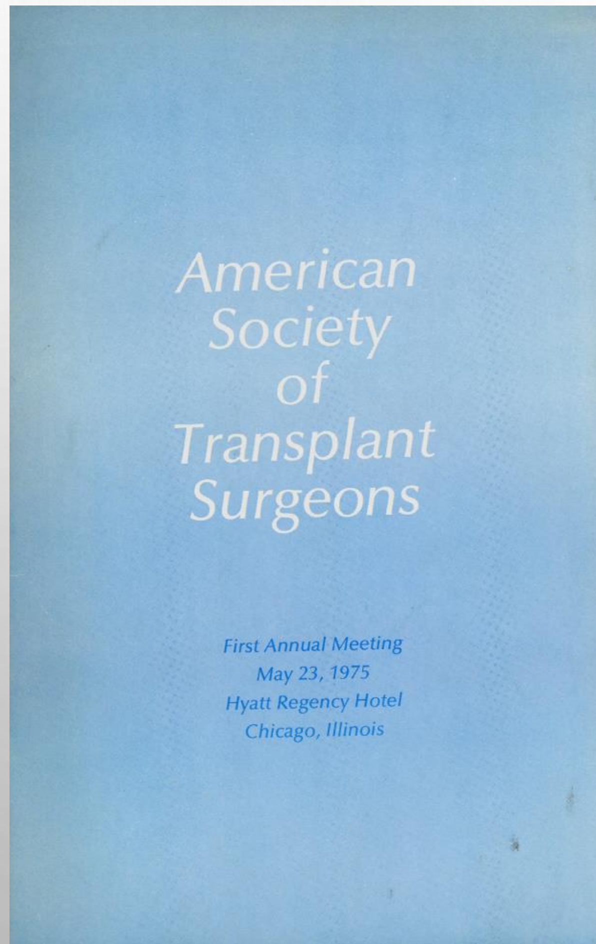
1975: SEOPF INCORPORATED- 18 CENTERS, PURCHASED COMPUTER SYSTEM, DEVELOPED ONLINE SYSTEM FOR MATCHING AND SHARING ORGANS.

1976: SEOPF BOARD OF DIRECTORS VOTED IN A ORGAN SHARING CONCEPT

1977: SEOPF NAMED COMPUTER SYSTEM *UNITED NETWORK FOR ORGAN SHARING* (UNOS) – REQUESTS FOR NON-SEOPF MEMBERS TO REGISTER POTENTIAL RECIPIENTS AND SHARING KIDNEYS.

1975 - FIRST ANNUAL MEETING OF ASTS

PATIENT SURVIVAL DD:79% TO 91%; **LRD 85% TO 100%**
GRAFT SURVIVAL DD: 49% TO 55 %; **LRD 73% TO 87%**



7. IMPROVED PATIENT SURVIVAL IN RENAL TRANSPLANTATION

Oscar Salvatierra, Jr., Donald E. Potter, Kent C. Cochrum, William J.C. Amend, Robert M. Duca, and Folkert O. Belzer (Department of Surgery, University of California, San Francisco, California)

Renal Transplant Registry data show current 1-year patient survival for recipients of primary cadaver kidneys to be 72%, and 89% for recipients of primary living related grafts. Sepsis continues to be the leading cause of death.

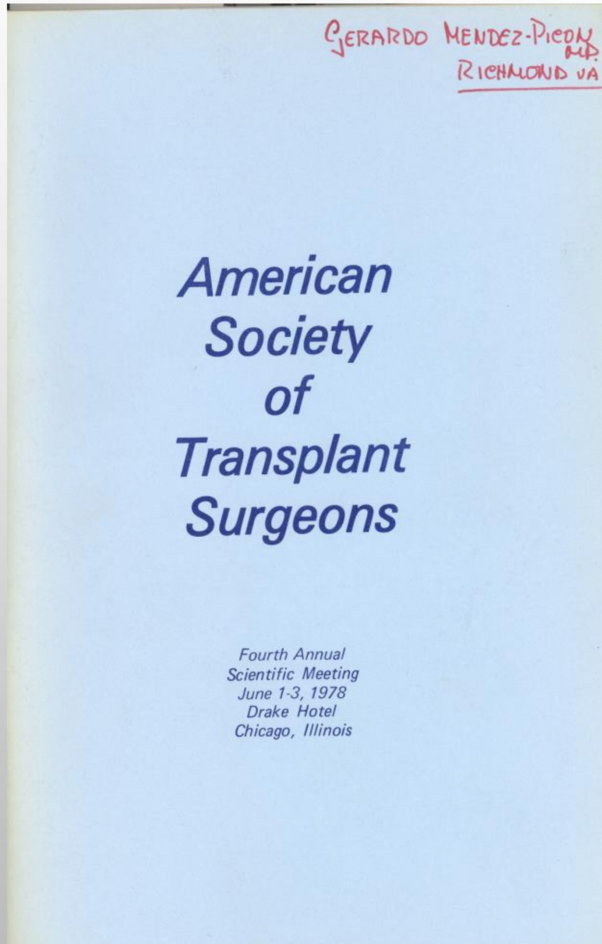
Since September, 1972, emphasis at this center has been placed on patient survival. We have accomplished this by abolishing prolonged high-dose immunosuppressive therapy after transplantation. Included in this regimen are: 1) no therapy after second rejection; 2) no therapy after first rejection if renal function does not return to normal; 3) no therapy for chronic rejection. The following results were obtained at one year:

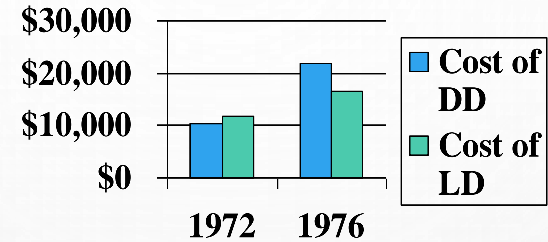
	Patient Survival		Graft Survival	
	Cadaver	Living Related HL-A non-iden.	Cadaver	Living Related HL-A non-iden.
Group I 1968-72	79% (198)	85% (117)	49% (236)	73% (128)
Group II	91% (205)	100% (24)	55% (218)	87% (24)

Numbers in brackets indicate total number of patients or grafts in each group. Cadaver graft survival numbers include first and multiple transplants. HL-A identical sibling transplants are an immunologically privileged combination, and 100% patient and graft survival were obtained in both Groups I and II.

These results show that graft survival is not jeopardized by accepting a policy of low immunosuppressive therapy, but that patient survival is significantly improved. This study also shows that cadaver renal transplantation can be performed with an equal or lower mortality than has been published for chronic dialysis.

THE FOURTH ANNUAL MEETING OF THE ASTS 1978





- INFLATIONARY ADJUSTMENT:
- THE MEDICAL PRICE INDEX ROSE FROM 127.1 TO 198.4 DURING THE PERIOD OF ANALYSIS

ERA OF IMMUNOSUPPRESSION

HOW TO HAVE THE SERVICE FOR ALL WHO NEED IT?

SIR ROY CALNE

- CYCLOSPORINE A APPROVED FOR USE 1983
  - CYCLIC POLYPEPTIDE 11 AMINO ACIDS
  - LIPOPHILIC, HYDROPHOBIC
  - METABOLITE OF TRICHODERM POLYSPORUM
    - 1978 – R. CALNE
    - 1978 – GREEN, ALLISON
    - 1976 – BUEGGER
    - 1976 - BOREL
- TACROLIMUS WAS ISOLATED IN 1984
  - APPROVED FOR USE IN 1994

THE GRAFT AND PATIENT SURVIVAL HAS IMPROVED WITH THE MIRACLE OF NEW MEDICATIONS

ETHICS IN ORGAN TRANSPLANTATION

- HOW CAN WE GET ENOUGH ORGANS?
- HOW ARE WE TO DISTRIBUTE THE ORGANS IN A FAIR AND EQUITABLE MANNER?
- SHOULD WE OFFER PAYMENT FOR DECEASED AND LIVING DONORS?
- SHOULD WE ENCOURAGE LIVING DONATION FROM NON-AMERICANS WHO WISH TO TRAVEL TO AMERICA FOR CASH OR OTHER MEDICAL CARE THAT COULD BE FINANCED THROUGH LIVING KIDNEY DONATION?

JULY 23,1983
RONALD REAGAN
RADIO ADDRESS BY THE PRESIDENT TO THE NATION

"TODAY I WANT NOT TO SPEAK OF GREAT NATIONAL ISSUES.

- INSTEAD I'M TAKING TO THE AIRWAVES IN HOPES WE CAN SAVE ONE LITTLE 11 MONTH OLD GIRL FROM TEXAS AND MANY LIKE HER.
- SHE HAS BUT 2-3 WEEKS TO LIVE UNLESS SHE RECEIVES A LIVER TRANSPLANT
- AN AIRFORCE JET IS STANDING READY IN CASE IMMEDIATE COMMERCIAL TRANSPORTATION NOT AVAILABLE
- HAVE YOUR PENCIL READY- IF YOU KNOW OF A POSSIBLE DONOR, CALL THE LIVING BANK IN HOUSTON TEXAS -800-528-2971"

1984 CONGRESS AUTHORIZED THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

"TO SUM IT UP, AIR FORCE 1 ISN'T A NATIONAL POLICY"
CONGRESSMAN TOM LUKEN, OHIO

- IDENTIFIED NEED FOR NATIONAL ALLOCATION SYSTEM FOR DECEASED DONOR ORGAN TRANSPLANT.
- BANNED THE PRACTICE OF PAYING FOR ORGAN DONATION FOR LIVING & DECEASED ORGAN.
- ESTABLISHED THE NATIONAL ORGAN PROCUREMENT AND TRANSPLANT NETWORK (OPTN) , 1986 AWARDED CONTRACT TO UNOS.

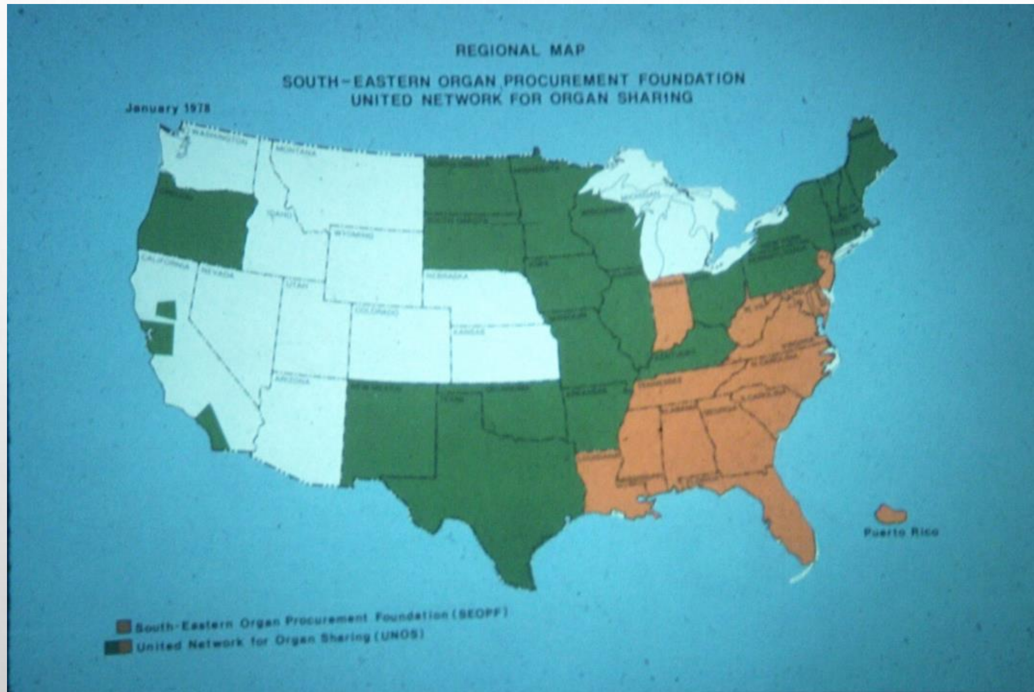
NATIONAL ORGAN TRANSPLANT ACT

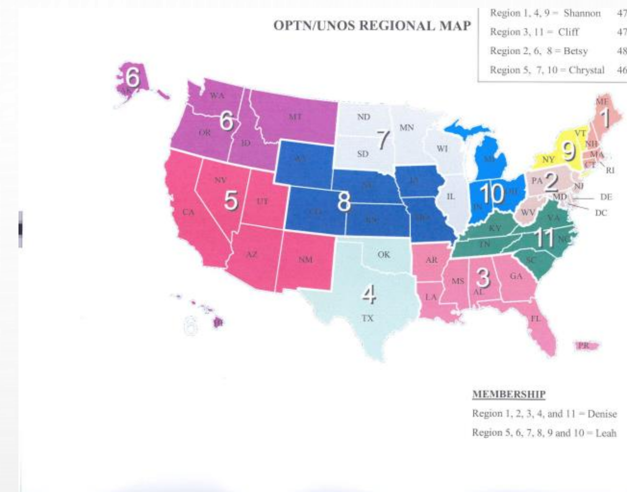
HEARINGS
BEFORE THE
SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT
OF THE
COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES
NINETY-EIGHTH CONGRESS
FIRST SESSION
ON
H.R. 4080
A BILL TO AMEND THE PUBLIC HEALTH SERVICE ACT TO AUTHORIZE FINANCIAL ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS, AND FOR OTHER PURPOSES

JULY 29, OCTOBER 17 AND 31, 1983

Serial No. 98–70

HRSA AWARDS CONTRACT TO UNITED NETWORK FOR ORGAN SHARING (UNOS)





1984: UNOS INCORPORATE- PRIVATE NON PROFIT ORGANIZATION TO OPERATE THE COMPUTERERIZED NATIONAL RECIPEINT REGISTRY AND TO COORDINATE PLACEMENT OF RECOVERED ORGANS THROUGH THE “ORGAN CENTER”.

1986: UNOS AWARDED FEDERAL CONTRACT BY HRSA TO ESTABLISH AND OPERATE THE NATIONAL OPTN.

1987: SEOPF DONATES/TRANSFERS COMPUTER HARDWARE, MATCHING SOFTWARE & ORGAN CENTER TO UNOS.

“HAPPILY EVER AFTER?”

THEN CAME MORE IMMUNOSUPPRESSION CHOICES

- FK506 – TACROLIMUS
- SIROLIMUS
- MYCOPHENOLATE MOFETIL
- POLYCLONAL ANTIBODIES
- MONOCLONAL ANTIBODIES

- STEROIDS -YES
- STEROIDS – NO
- INDUCTION – YES
- INDUCTION- NO

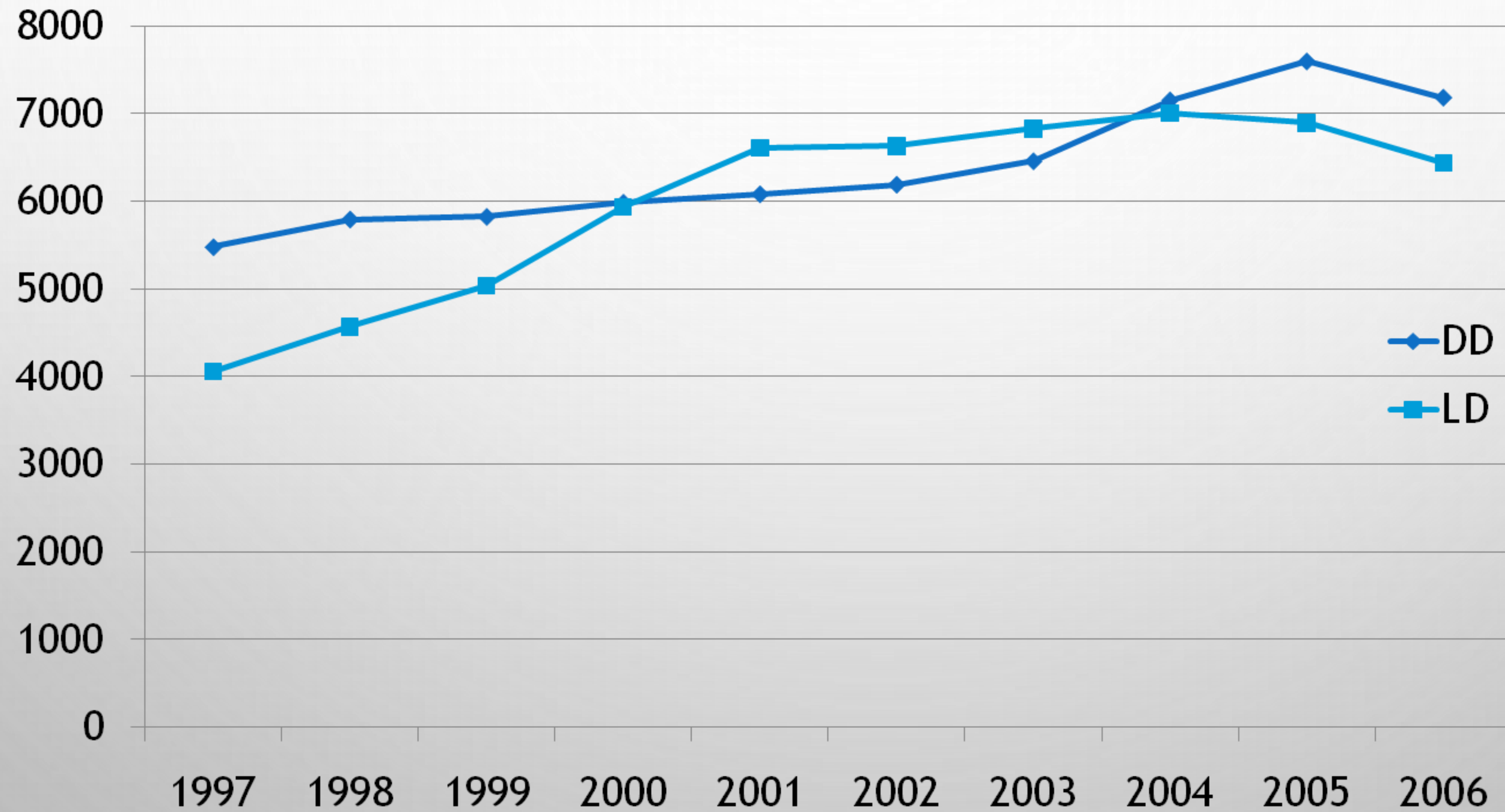
They all cost money

IMPROVING LIVING DONOR OPTION

- LAPAROSCOPIC RETRIEVAL LLOYD RATNER, M.D.
  - 1995 AT JOHNS HOPKINS

- BETTER UTILIZATION OF LIVING DONORS:
  - BROADER SHARING- 2 OR MORE SWAPS
  - "GOOD SAMARITAN" DONOR
  - PROXY DONOR
  - PRA REDUCTION PROTOCOLS
  - ABO INCOMPATIBLE KIDNEY TRANSPLANTS

DECEASED DONOR & LIVING DONOR



ERA OF INCREASING REGULATIONS BY HHS

CMS & HRSA

TRANSPLANT PROGRAM PRACTICES, OUTCOMES AND LIVING ORGAN DONOR DEATHS RAISES QUESTIONS

New Yorker Dies After Surgery To Give Liver Part to Brother

State Fines Mount Sinai $66,000 and Bans Live Liver Transplants Indefinitely

By Lydia Polgreen
Aug. 31, 2002

<u>LIVING LIVER DONORS:</u>
2001: 524
2002: 363
2009: 219

CONSENSUS CONFERENCES TO OUTLINE CARE OF THE LIVING ORGAN DONOR

- CONSENSUS STATEMENT OF THE LIVE ORGAN DONOR": JAMA, DECEMBER 12, 2000-VOL 284, NO.22
- 2002 NEW YORK STATE COMMITTEE ON QUALITY IMPROVEMENT IN LIVING LIVER DONATION AT HTTP://WWW.HEALTH.STATE.NY.US
- A REPORT OF THE AMSTERDAM FORUM ON THE CARE OF THE LIVE KIDNEY DONOR: DATA AND MEDICAL GUIDELINES. TRANSPLANTATION 2005;79 S53-S66.
- A REPORT OF THE VANCOUVER FORUM ON THE CARE OF THE LIVING ORGAN DONOR: LUNG, LIVER, PANCREAS AND INTESTINE: TRANSPLANTATION 2006;81(10):1373-1385
- 2008 DECLARATION OF ISTANBUL ON ORGAN TRAFFICKING AND TRANSPLANT TOURISM

ADVISORY COMMITTEE ON ORGAN TRANSPLANT (ACOT)

- 2001 THE ADVISORY COMMITTEE ON ORGAN TRANSPLANTATION (ACOT) WAS ESTABLISHED TO ASSIST THE HHS SECRETARY IN:
  - ENHANCING ORGAN DONATION
  - ENSURING THAT THE SYSTEM OF ORGAN TRANSPLANTATION IS GROUNDED IN THE BEST AVAILABLE MEDICAL SCIENCE
  - ASSURING THE PUBLIC THAT THE SYSTEM IS AS EFFECTIVE AND EQUITABLE AS POSSIBLE
  - INCREASING PUBLIC CONFIDENCE IN THE INTEGRITY AND EFFECTIVENESS OF THE TRANSPLANTATION SYSTEM

ACOT REPORT NOVEMBER 2002

November 18-19, 2002, in Arlington, Virginia, committee unanimously agreed on its first 18 consensus recommendations.

The first day of that meeting was devoted by the Committee to responding to Secretary Thompson's specific request to them that they look into **several concerns he had with respect to the process of live organ donation and transplantation — particularly regarding the kidney, liver and lung — so as to ensure that the donation and transplantation process would be as safe and effective as possible, for both the living organ donor and the recipient of the donor's organ.**

ACOT believes that the implementation of these first seven recommendations will ensure the protection of potential living donors and simultaneously enhance the effectiveness of living donation and transplantation.

ACOT RECOMMENDATIONS:

PROTECTION OF POTENTIAL LIVING DONORS AND SIMULTANEOUSLY ENHANCE THE EFFECTIVENESS OF LIVING DONATION AND TRANSPLANTATION.

RECOMMENDATION 1: THAT THE FOLLOWING ETHICAL PRINCIPLES AND INFORMED CONSENT STANDARDS BE IMPLEMENTED FOR ALL LIVING DONORS.

THE PERSON WHO GIVES CONSENT TO BECOMING A LIVE ORGAN DONOR MUST BE:

- COMPETENT (POSSESSING DECISION MAKING CAPACITY)
- WILLING TO DONATE
- FREE FROM COERCION
- MEDICALLY AND PSYCHOSOCIALLY SUITABLE
- FULLY INFORMED OF THE RISKS AND BENEFITS AS A DONOR AND
- FULLY INFORMED OF THE RISKS, BENEFITS, AND ALTERNATIVE TREATMENT AVAILABLE TO THE RECIPIENT.

ACOT RECOMMENDATIONS FOR LIVING DONATION

- **RECOMMENDATION 2:** THAT EACH INSTITUTION THAT PERFORMS LIVING DONOR TRANSPLANTATION PROVIDE AN INDEPENDENT DONOR ADVOCATE TO ENSURE THAT THE INFORMED CONSENT STANDARDS AND ETHICAL PRINCIPLES DESCRIBED ABOVE ARE APPLIED TO THE PRACTICE OF ALL LIVE ORGAN DONOR TRANSPLANTATION.
- **RECOMMENDATION 3:** THAT A DATABASE OF HEALTH OUTCOMES FOR ALL LIVE DONORS BE ESTABLISHED AND FUNDED THROUGH AND UNDER THE AUSPICES OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.
- **RECOMMENDATION 4:** THAT SERIOUS CONSIDERATION BE GIVEN TO THE ESTABLISHMENT OF A SEPARATE RESOURCE CENTER FOR LIVING DONORS AND THEIR FAMILIES.
- **RECOMMENDATION 5:** THAT THE PRESENT PREFERENCE IN OPTN ALLOCATION POLICY — GIVEN TO PRIOR LIVING ORGAN DONORS WHO SUBSEQUENTLY NEED A KIDNEY — BE EXTENDED SO THAT ANY LIVING ORGAN DONOR WOULD BE GIVEN PREFERENCE AS A CANDIDATE FOR ANY ORGAN TRANSPLANT, SHOULD ONE BECOME NEEDED.
- **RECOMMENDATION 7:** THAT A PROCESS BE ESTABLISHED THAT WOULD VERIFY THE QUALIFICATIONS OF A CENTER TO PERFORM LIVING DONOR LIVER OR LUNG TRANSPLANTATION.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-08-25

DATE: **June 13, 2008**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy - Organ Transplant Program Interpretive Guidelines

THE IDENTICAL TWIN KIDNEY TRANSPLANT 1954: CONVERSATION WITH THE DONOR, RONALD

- RONALD ASKED, "WILL THE HOSPITAL BE RESPONSIBLE FOR MY HEALTHCARE FOR THE REST OF MY LIFE?"
- DR. HARRISON, THE SURGEON FOR THE DONOR , SAID " OF COURSE NOT….BUT, RONALD DO YOU THINK ANYONE IN THIS ROOM WOULD EVER REFUSE TO TAKE CARE OF YOU IF YOU NEEDED HELP?
- RONALD UNDERSTOOD, HIS FUTURE DEPENDED UPON OUR SENSE OF PROFESSIONAL RESPONSIBILITY RATHER THAN ON LEGAL ASSURANCES.

THIS COURSE IS ORGANIZED FOR EDUCATION ON THE DETAILS THAT OUR POLICY EXPERTS HAVE CODED INTO THE RULES AND REGULATIONS FOR THE CARE OF THE LIVING DONOR.