

**Changing Practice Based on Evidence: How It Improved Our Practice**

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**Organ Procurement**

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***“The haemodynamic effects of adjunctive hormone therapy in potential heart donors: a prospective randomized double-blind factorially designed controlled trial”***  
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- Purpose
  - Investigate the individual or combined effects of methylprednisolone (MP) and T3 on donor heart function in potential donors

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### Methods

Study Design

- January 2004 – April 2006
- Donors who met the following:
  - Age 16 – 65
  - Authorization for heart donation
  - No reported hx of ischemic heart disease
  - No major thoracic trauma
  - In an ICU w/in 2 hours of heart tx center

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### Initial assessment & management

ASAP after consent:

- Research fellow responded on site to draw thyroid functions tests
- Inserted PA catheters
  - MAP, CVP, PAWP, CI/CO, SVR, R & LVSWI captured
- Study medications were administered

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### Initial assessment & management

- Donors were randomly assigned to a study group using a computerized model
  - MP only, T3 only, Combination, Placebo
- Drugs were pre-prepared in identical volumes in code-labeled syringes by non-involved recipient center staff
- All medical, nursing and technical staff were blinded to the treatment allocation

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### Donor Management

- Goals to manage to were:
  - CI >2.5
  - CVP/PAWP  $\leq$  12
  - MAP 65 – 85
  - SVR 800-1200
  - Hgb  $\geq$  10
- Pre-study inotropes were weaned and replaced with Vasopressin
- Blood sugar control with insulin
- Hypothermia prevented

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### Endpoints & Statistics

- Primary endpoint was the difference in the final CI between the groups
- Secondary endpoints
  - Comparison of RVSWI/LVSWI
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### Results

Donor Groups

Group	Count
Placebo	21
T3	20
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**Results, cont.**

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  - 80% were on site consultations
- 62 donors in non-intensivist group
- Patient demographic information collected
  - Age, gender, race, COD
- Type of donor hospital
- Time from authorization to OR
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## Results

- More anoxic patients in non-intensivist group
- More intensivist consults in "A" hospitals
  - 94% vs 82%
- DMGs met 36% vs 24% with intensivists
- Time of donor case longer w/ intensivists
  - 21.3hrs vs 16.3 hrs
- More OTPD 3.52 vs. 3.08 in intensivist group
- Significantly more lungs tx'd in intensivist group
  - 31% vs 10%
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# HEART TRANSPLANT

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## Virtual Crossmatching

- TC limited acceptance of organs locally for highly sensitized patients
- Disadvantages patients with rare HLA antigens
- “Virtual” crossmatches are performed
- Retrospective crossmatches confirm virtual testing

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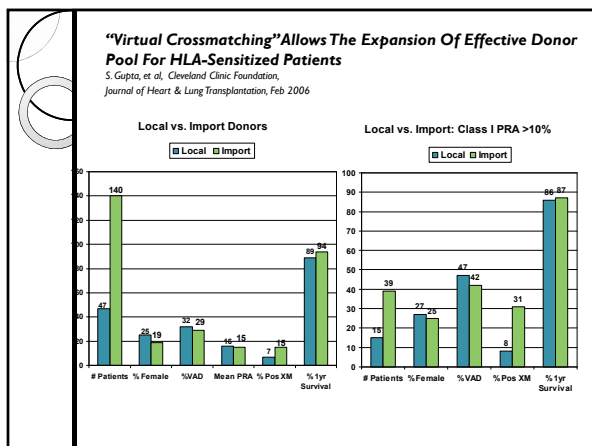
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**Donor-to-Recipient Size Mismatch**

- Recent study shows 50% survival at 10 years for over 70,000 patients
- Organ deficit led to use of marginal donors nationwide
- Established criteria uses cardiac allografts within 20% of recipients weight
- Large multi-center study analyzed UNOS data

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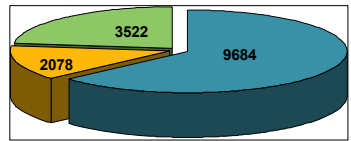
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**N = 15,284**  
1999 through 2006

- 3 groups donor-to-recipient weigh ratio



Category	Count
within 20%	9684
undersized	2078
oversized	3522

■ within 20% ■ undersized ■ oversized

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**Impact of Donor-to-Recipient Weight Ratio on Survival After Heart Transplantation: Analysis of UNOS Database**  
Nishant D. Patel, et al.  
Circulation, September 30, 2008

- Weight ratio not predictor of mortality
- Recipients w/ high PVR receiving undersized hearts had poor survival
- Male recipients w/ high PVR receiving heart from female donor had worse survival than male-to-male donation
- Under-sizing hearts in select recipients should be considered

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### Donor Substance Use/Abuse

- Retrospective study reviewed short-term and long-term outcomes
  - 689 patients
  - Final cohort 150 (22%) met criteria
- Use/abuse defined as
  - 2 or more ETOH drinks/day
  - 1ppd smoker greater than 5 years
  - Habitual marijuana, cocaine, methadone, opiate or IV heroin use

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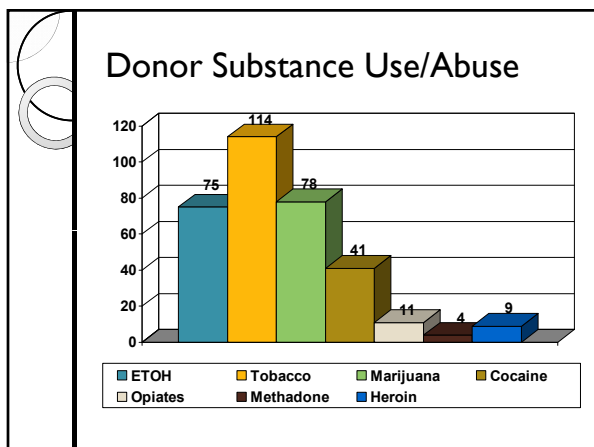
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### The Effect of a Donor's History of Active Substance on Outcomes Following Orthotopic Heart Transplantation

Kenneth Shea, et al, European Journal of Cardio-Thoracic Surgery, 2007

- Methods
  - Patient/Donor criteria
  - Procurement
  - Immunosuppressant therapy
  - Post-transplant ECHO
  - Transplant-associated CAD (TCAD)
- Results
  - Short-term outcomes
  - Pre-discharge ventricular function
  - Risk of TCAD
- Conclusion
  - Substance abuse has no negative impact
  - Virus positive organs have high risk for conversion

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	<ul style="list-style-type: none"><li>◦ <b>LUNG TRANSPLANT</b></li></ul>
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	<p><b>3 Words</b></p> <ul style="list-style-type: none"><li>• L</li><li>• A</li><li>• S</li></ul>
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	<ul style="list-style-type: none"><li>• <b>1999 DHHS final rule regarding organ allocation</b></li><li>• <b>The LAS defined</b><ul style="list-style-type: none"><li>◦ transplant benefit measure minus the waiting list urgency measure</li><li>• <u>transplant benefit measure = posttransplant survival measure - wait list urgency measure;</u> <u>raw LAS = transplant benefit measure - wait list urgency measure; raw LAS = posttransplant survival measure - 2x (wait list urgency measure).</u></li></ul></li></ul>
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## Early data

- **single-center experience**
  - **data limited to the first 2 months after the change to the LAS**
  - **statistically significant increase in the percentage of patients receiving a transplant for IPF, with a decrease in the proportion of patients receiving a transplant for COPD**
  - **Thirty-day survival was not statistically different before and after the LAS took effect**

Hadjilovs, D, Abuel, YN, Coston, JD. Early results of lung transplantation after implementation of the new lung allocation score [abstract]. Heart Lung Transplant 2002;31(suppl 1):144

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## UNOS data

- **2006 OPTN/Scientific Registry of Transplant Recipients (SRTR) annual report (covering 1996 to 2005)**
  - **Difficult to interpret- not subclassified into pre-LAS and post-LAS implementation**
  - **The changes in distribution of underlying diseases leading to transplantation are seen at the national level**
    - **IPF representing 28% of transplants in 2005**
      - **up from 24% in 2004.**
    - **Candidates with IPF also made up a smaller percentage of the active waiting list at the end of 2005 (12% vs 18%)**
    - **Time by which 25% of candidates have received a transplant dropped substantially in 2005 to 54 days, down from 183 days in 2004.**
    - **Death rate while on the waiting list continued to fall in 2005, at a faster rate than in previous years**

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## Mid-long range data

- **Survival data are limited by the lack of mandatory reporting between the time of discharge from the transplant admission and the 1-year posttransplant mark**
  - **Trend toward slightly increased mortality in the 2005 cohort**
    - **across all diagnosis groups**
    - **not statistically significant.**

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**Future**

- **One of the advantages of the LAS is its flexibility.**
- **Provision of implementation is that it must be reevaluated every 6 months after an initial 3-year period**
- **Allows model to evolve as the predictors of mortality change with the new allocation system**

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**Future**

- **As more data become available**
  - **the change in variables over time while on the waiting list**
  - **new predictor variables**

**More insight into proper allocation of organs**

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**Procurement**

- **Anesthesia factors associated with early graft function**
  - **107 consecutive lung transplants**
  - **donor, recipient and surgical factors constant**

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### Lung Procurement

- On multivariate analysis, increasing volume of intraoperative colloid, comprising predominantly Gelofusine® (succinylated gelatin), was independently associated with a lower  $PaO_2/FIO_2$

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### Lung Procurement

- Inverse relationship between volume of intraoperative colloid and early **lung allograft function**. **The association persists, despite detailed sensitivity analyses and adjustment for potential confounding variables**

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### Lung Summary

- LAS
- Less colloid intraop

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# LIVER TRANSPLANT

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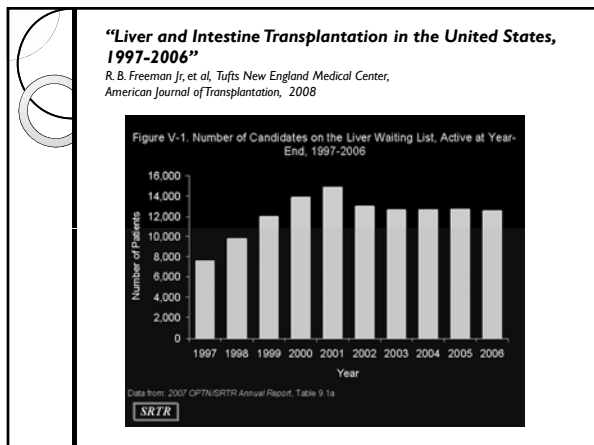
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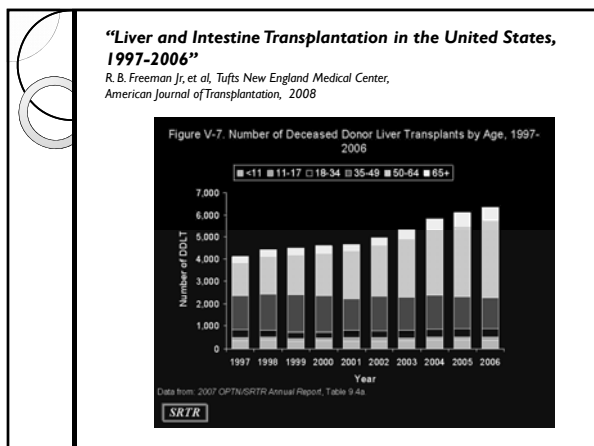
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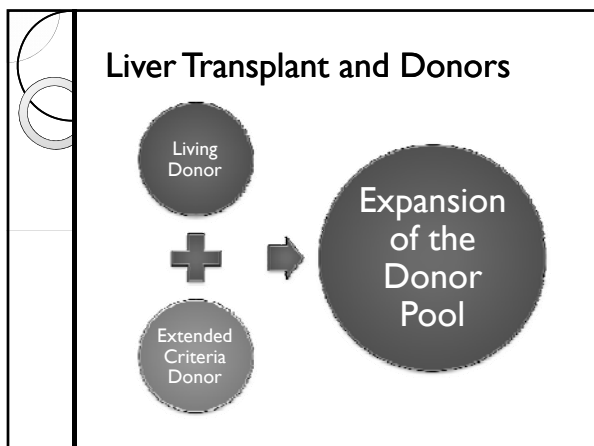
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### History of Living Donor Liver Transplant

- Potential to reduce recipient mortality
  - Urgent need of transplant
  - May otherwise be excluded
- Outcomes comparable to deceased donor
  - 1 year patient survival 89.1%
  - 3 year patient survival 80.3%

Two black and white photographs showing medical professionals in an operating room. The top photo shows a close-up of a surgeon's face and hands. The bottom photo shows a wider view of the surgical team performing a procedure.

Said & Lucey, 2008

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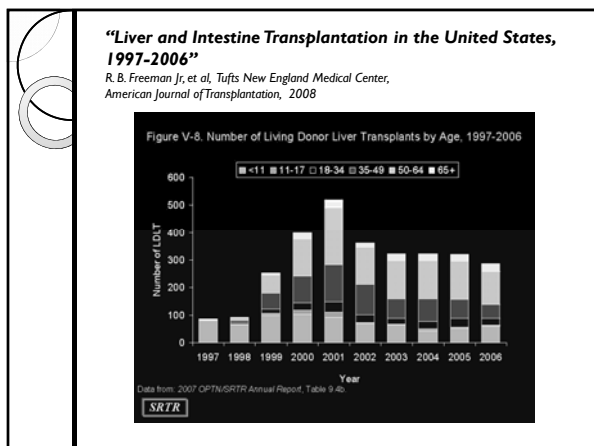
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*"Living donor liver transplantation in the United States: Identifying donors at risk for perioperative complications".*  
 S. Patel, et al, University of Rochester Medical Center  
 American Journal of Transplant, 2007

- Live donor liver transplant
  - Donor safety is a primary concern
- Audit of LDLT from 2001 to 2005
  - 433 right and left lobe donors reviewed
  - 3 centers
  - One perioperative death (0.23%)
  - Overall complication rate was 29%, with 3.5% experience severe complications
  - Older donor age (>50 years) was associated with a four fold risk of complications
- Standardized tool to identify donors

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*"Waitlist mortality decreases with increased use of extended criteria donor liver grafts at adult liver transplant centers"*  
 N.R. Barshes, et al, Baylor College of Medicine  
 American Journal of Transplantation, 2007

- Extended criteria donor
  - Grafts more commonly associated with poor function and decreased survival

Condition	Percentage
Older donors	15%
Donation after cardiac death	25%
Hepatitis B and Hepatitis C	15%
Steatosis	25%
Prolonged ischemia time	20%

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## Donor Age

- UNOS
  - 1/3 of donors are 50+ years of age
- Effect of Donor Age on Graft Survival
  - 1990-1998 UNOS Data

Donor Age	1 year	3 year
18-49 years	83.5%	72%
50-64 years	77.6%	63.6%
- Donor Age 70+ years
  - 1991-1995 (Emre et al, 2006)

	1 year
Graft Survival	85%
Patient Survival	91%

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## Donation after Cardiac Death

**Liver Transplants using DCD Donors and Number of Liver Transplant Programs that Performed DCD Liver Transplants by Year (1/1/2000 to 12/31/2006)\***

Year of Transplant	Total Donors N	DCD Donors N	DCD Donors % of Total	DCD Liver TX Programs N
2000	4,497	39	0.9%	11
2001	4,485	48	1.1%	20
2002	4,597	76	1.7%	28
2003	5,043	110	2.2%	38
2004	5,458	178	3.3%	42
2005	5,679	259	4.6%	54
2006	5,849	277	4.7%	60
Total	35,598	1,007	2.8%	78

\* Excludes multi-organ transplants

Data from: OPTN Analysis, May 2007

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*Optimal utilization of donor grafts with extended criteria: A single-center experience in over 1000 liver transplants*  
 Cameron et al  
 Annals of Surgery, 2006

- Retrospective study examined extended criteria donors
  - Age, hospital, cold and warm ischemia times
- Advanced recipient age and urgent recipient status associated with an increased risk of death
  - ECD grafts should not be used for critically ill recipients
- Outcomes with ECDs can be excellent
  - Appropriate recipient and donor matching

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*Use of extended criteria livers decreases wait time for liver transplantation without adversely impacting post-transplant survival*  
 AJ Tector et al, Indiana University School of Medicine  
 Annals of Surgery, 2006

- Graft and patient survival for standard and extended criteria donors
  - 2001 to 2005

N = 571

388  
(68%)  
ECD

183  
(32%)  
SD

Extended Criteria Donor
Age > 59 years
BMI > 34.9
Maximum AST or ALT > 500
Maximum bilirubin > 2.0
Peak serum sodium > 170
HBC/HCV/HTLV reactive
Donation after cardiac death
Cold ischemia time > 12 hours
ICU stay > 5 days
3 or more pressors
Extensive alcohol abuse
Cancer (non skin) history
Active bacteremia

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*Use of extended criteria livers decreases wait time for liver transplantation without adversely impacting post-transplant survival*  
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- Wait list from 257 → 30 patients
- Graft survival not statistically different between two donor groups
  - Donor age >60 years was only factor associated with decreased graft and patient survival
- Liver grafts from ECD can be used to dramatically reduce waitlist time with outcomes comparable to those for standard donor

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◦ **KIDNEY TRANSPLANT**

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**JOHNS HOPKINS LEADS FIRST 12-PATIENT, MULTICENTER “DOMINO DONOR” KIDNEY TRANSPLANT**

- Simultaneous and Multi-State Procedure
  - Kidney Paired Donation (KPD)
  - Group of incompatible donor-recipient pairs
    - Recipients coming to one of the 3 hospitals with a willing donor who is not compatible by blood or tissue
    - Match them with other pairs in same predicament
- Previous six-way domino successful
- 1<sup>st</sup> grand scale domino
  - Involving 2 other hospitals

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**Domino Donor Kidney Cont.**

- Serve as a blueprint for national match in which kidneys will be transported around the country
- Resulting in an estimated 1,500 additional transplants each year



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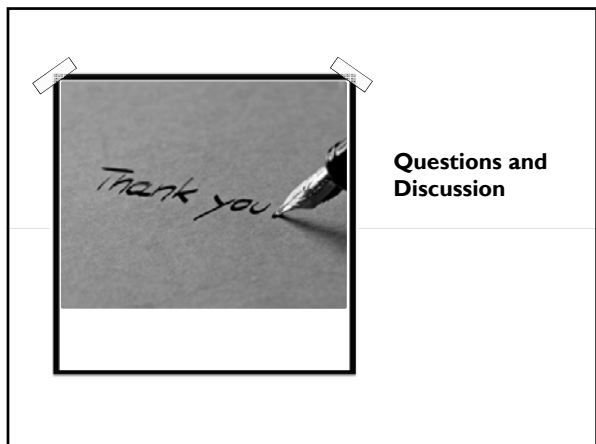
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