Rôle d'une agence de promotion de la transplantation d'organes.

Francis L. Delmonico

Professor of Surgery
Harvard Medical School

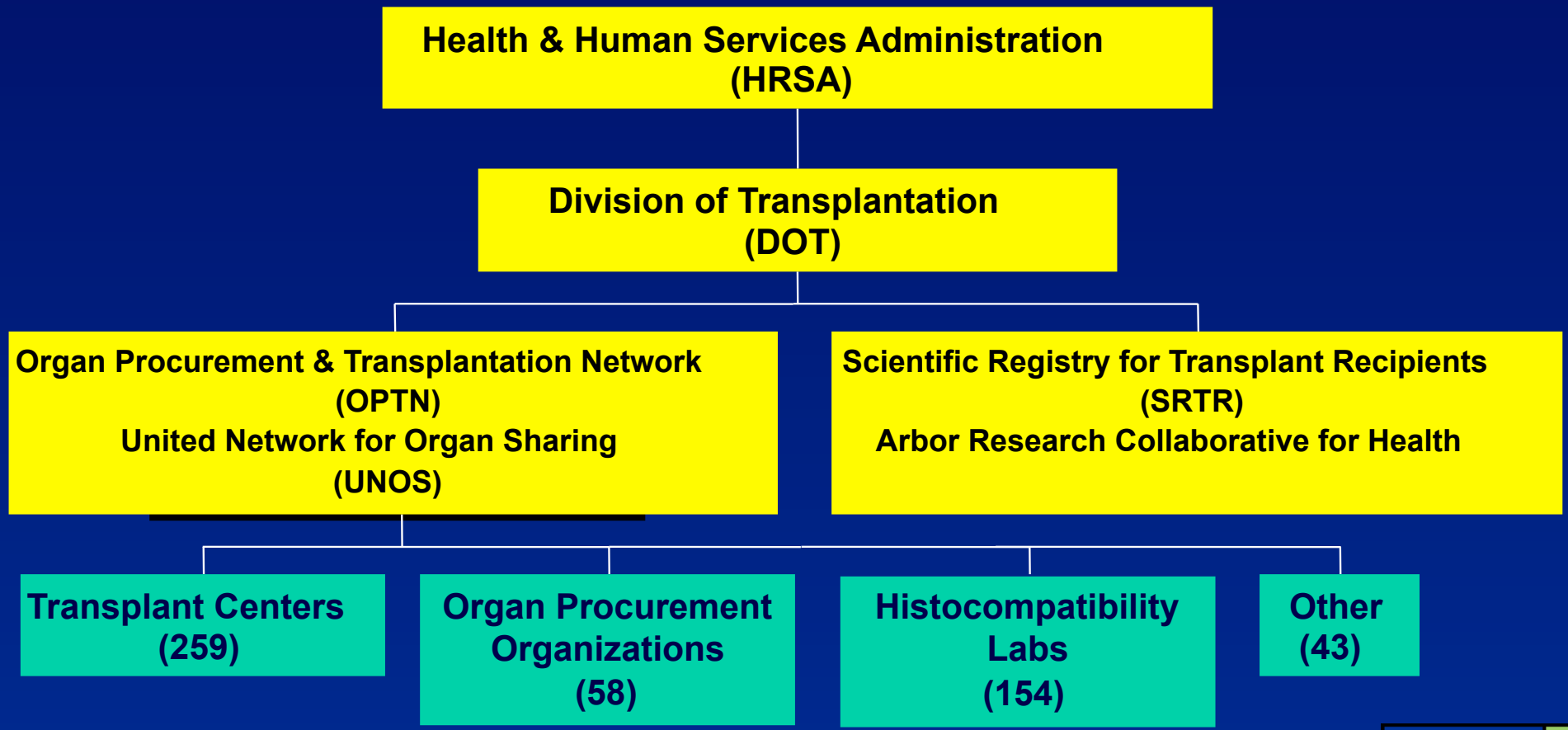
Director
Medical Affairs
The Transplantation Society

Transplantation Center
Massachusetts General Hospital

Medical Director
New England Organ Bank

Past President
UNOS / OPTN

Organizational Structure of Transplantation in the US



OPTN

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National Organ Transplant Act

- Task Force
- Prohibited buying & selling organs
- Created the modern OPO system
- Scientific Registry
- Organ Procurement & Transplantation Network (OPTN)

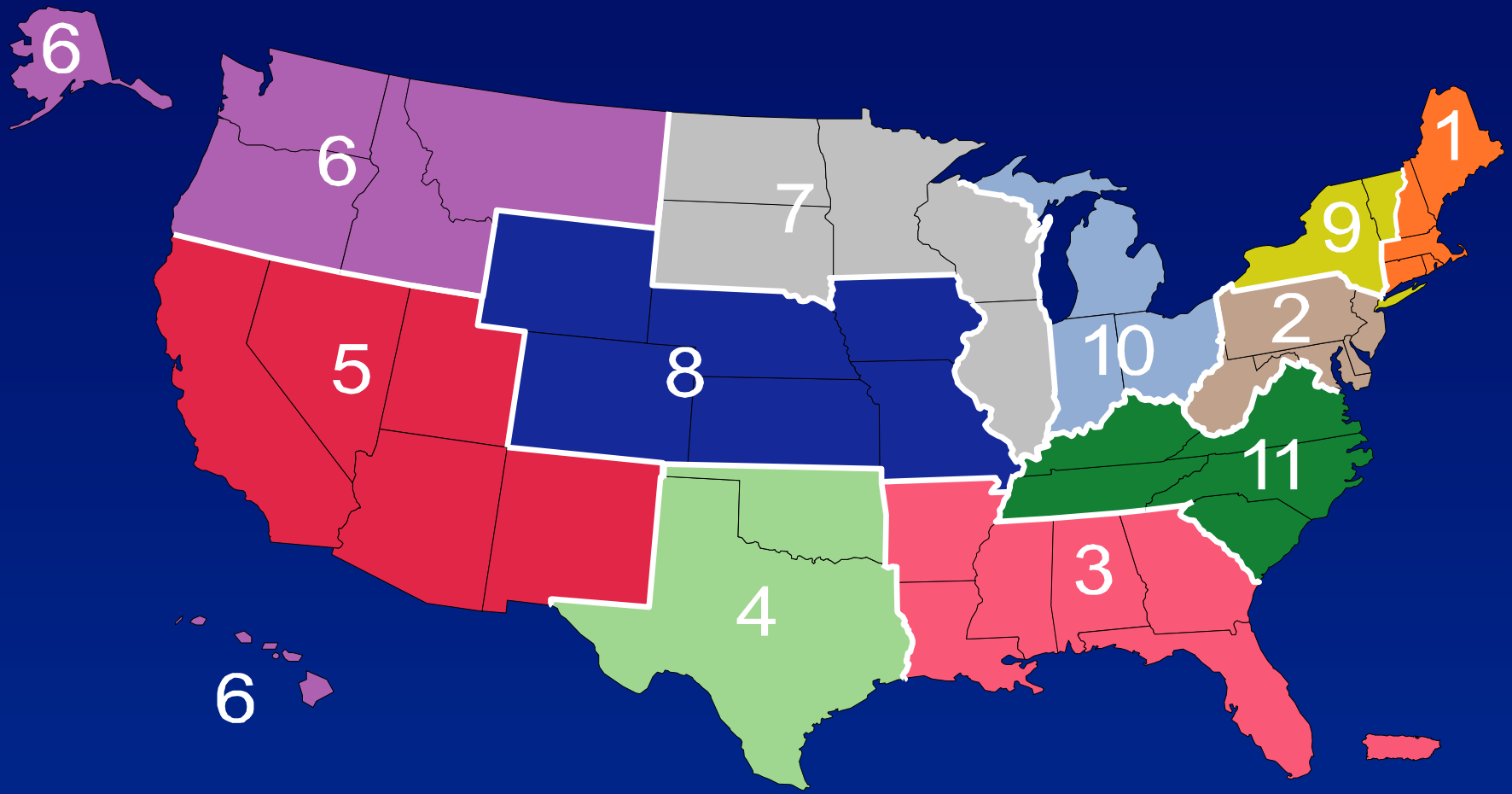
What is the OPTN?

- The OPTN was established by NOTA (National Organ Transplant Act) in 1984 42 U.S.C. §§ 273
- The OPTN is the network that links all of the professionals involved in the (solid) organ donation and transplantation system in the United States

The OPTN's major responsibilities include the following:

- **Organ availability** - Increasing organ donation rate + number of organs transplanted;
- **Organ allocation** - Increasing the benefit and equity of transplantation for transplant recipients by the development and maintenance of policies for the equitable allocation
- **Policies and standards** – Improving the operation of the network through the development, implementation, operation, and maintenance of policies and standards that structure nation's system for organ procurement and transplantation;
- **Data collection** – Improving overall quality of the OPTN's work through the collection and dissemination of data pertaining to organ procurement and transplantation.

OPTN / UNOS Regions



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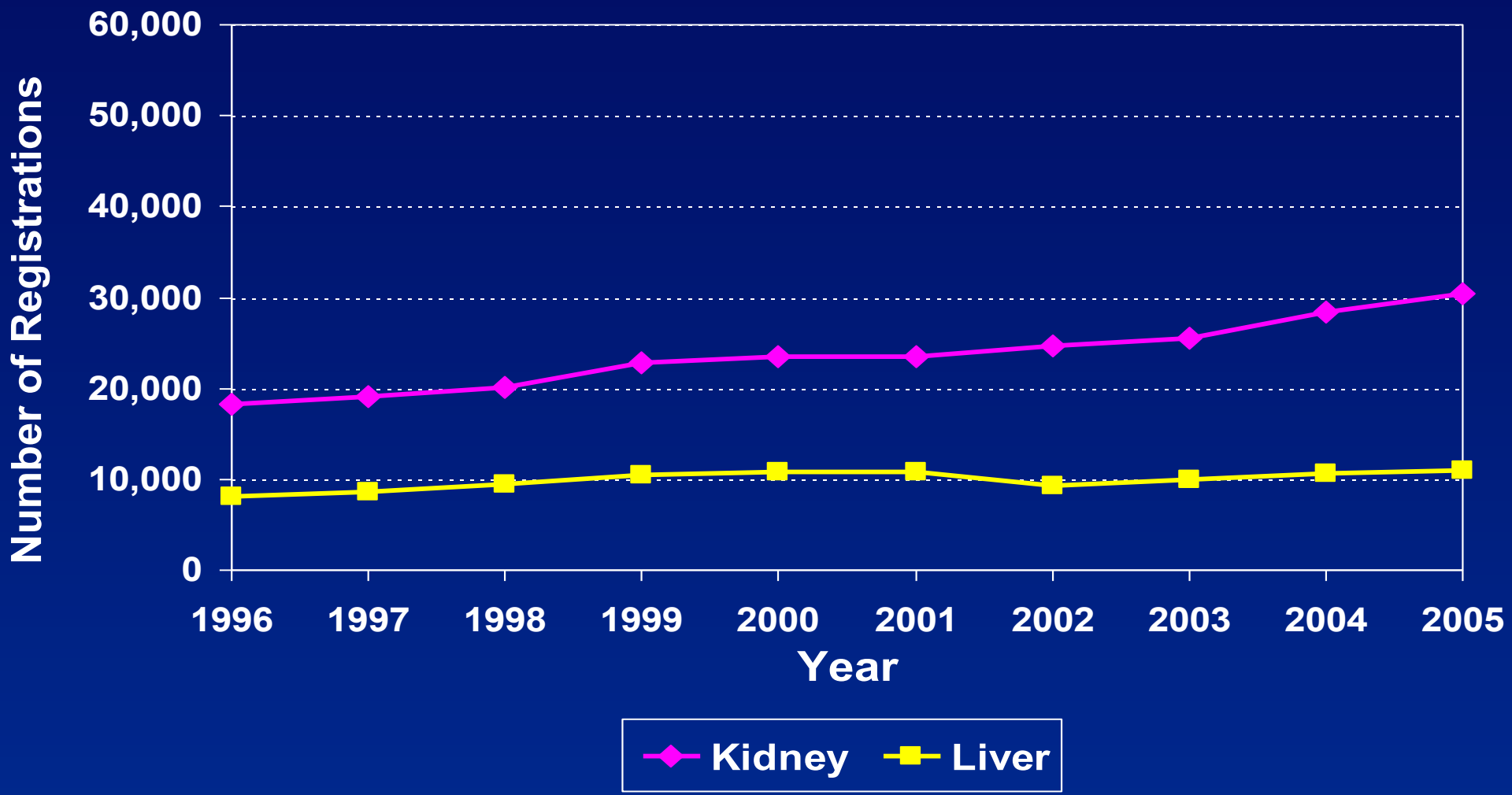
The Final Rule (1)

- In addition to NOTA and the OPTN Contract, OPTN activities are governed by the OPTN Final Rule, 42 CFR Part 121.
  - Became effective March 16, 2000
  - Further defines terms and conditions for operation of the OPTN

FINAL RULE

- Required by Final Rule and Contract with HRSA
- OPTN Must Have Survey Instruments, Peer Review Process and Data Systems to
  - Conduct Ongoing and Periodic Reviews of Each Transplant Center and OPO
  - Verify Compliance With the Final Rule and OPTN Policies

Waiting List Additions 1996-2005
U.S.



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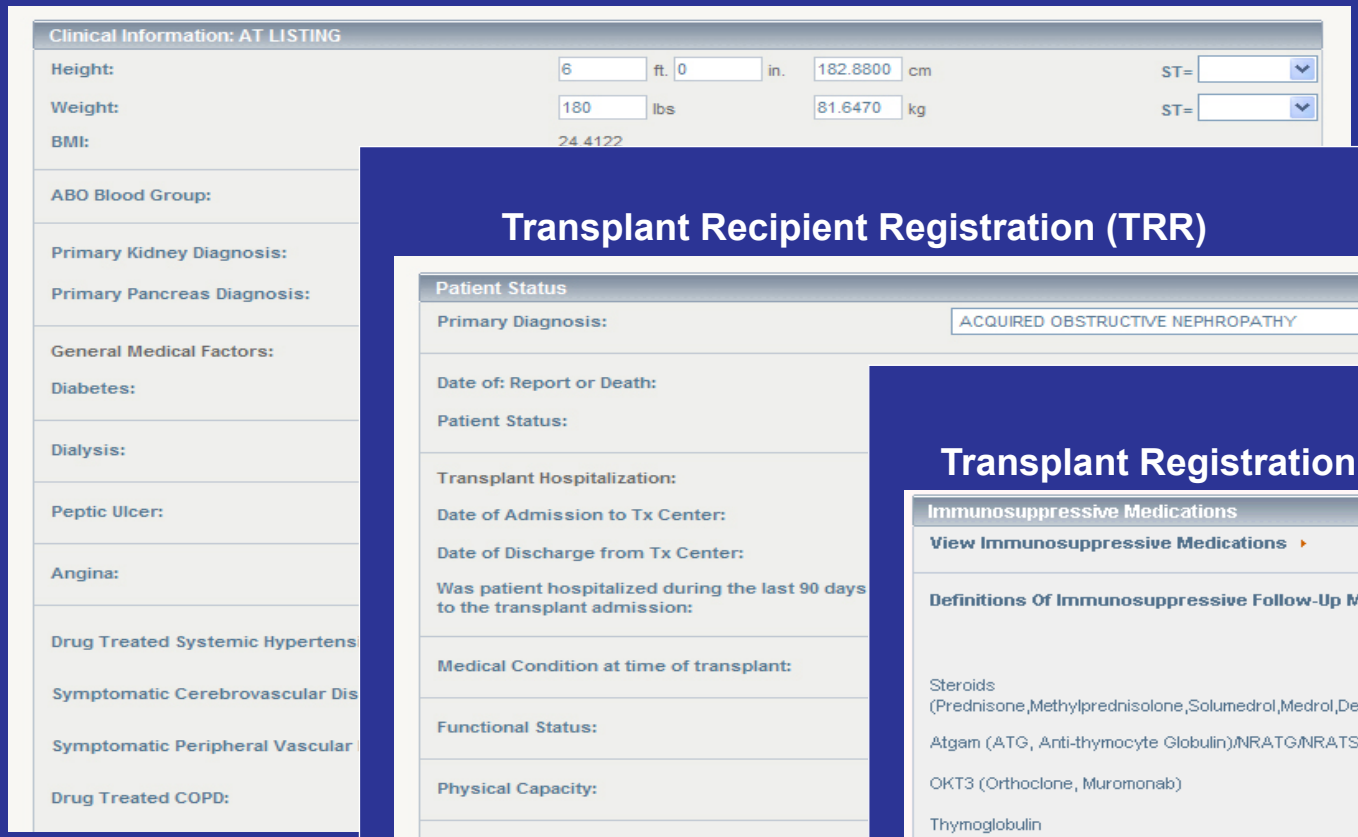
UNet

Data Collection Systems and Process

Transplant Candidate Registration (TCR)



Transplant Recipient Registration (TRR)

Transplant Registration Follow-up (TRF)

OPTN

Event-driven data collection

Pre-Transplant

- Candidate data
- Medical condition
- Primary diagnosis
- Lab results and diagnostic tests
- General medical factors
- Malignancies

Transplant

- Donor data
- Patient status
- Graft status
- Viral detection
- Acute rejection episodes
- Immunosuppressive treatment

Post-Transplant

- Recipient data
- Patient status
- Graft status
- Rejection information
- Malignancies
- Immunosuppressive treatment

What is the system?

UNet[SM] is a secure, Web-based medical informatics system critical to organ donation and transplantation.

The system includes applications to:

- Manage the national patient waiting list
- Handle all organ matching and allocation
- Track pre- and post-transplant patient data, following the patient for the remainder of life

Data is collected for the following:

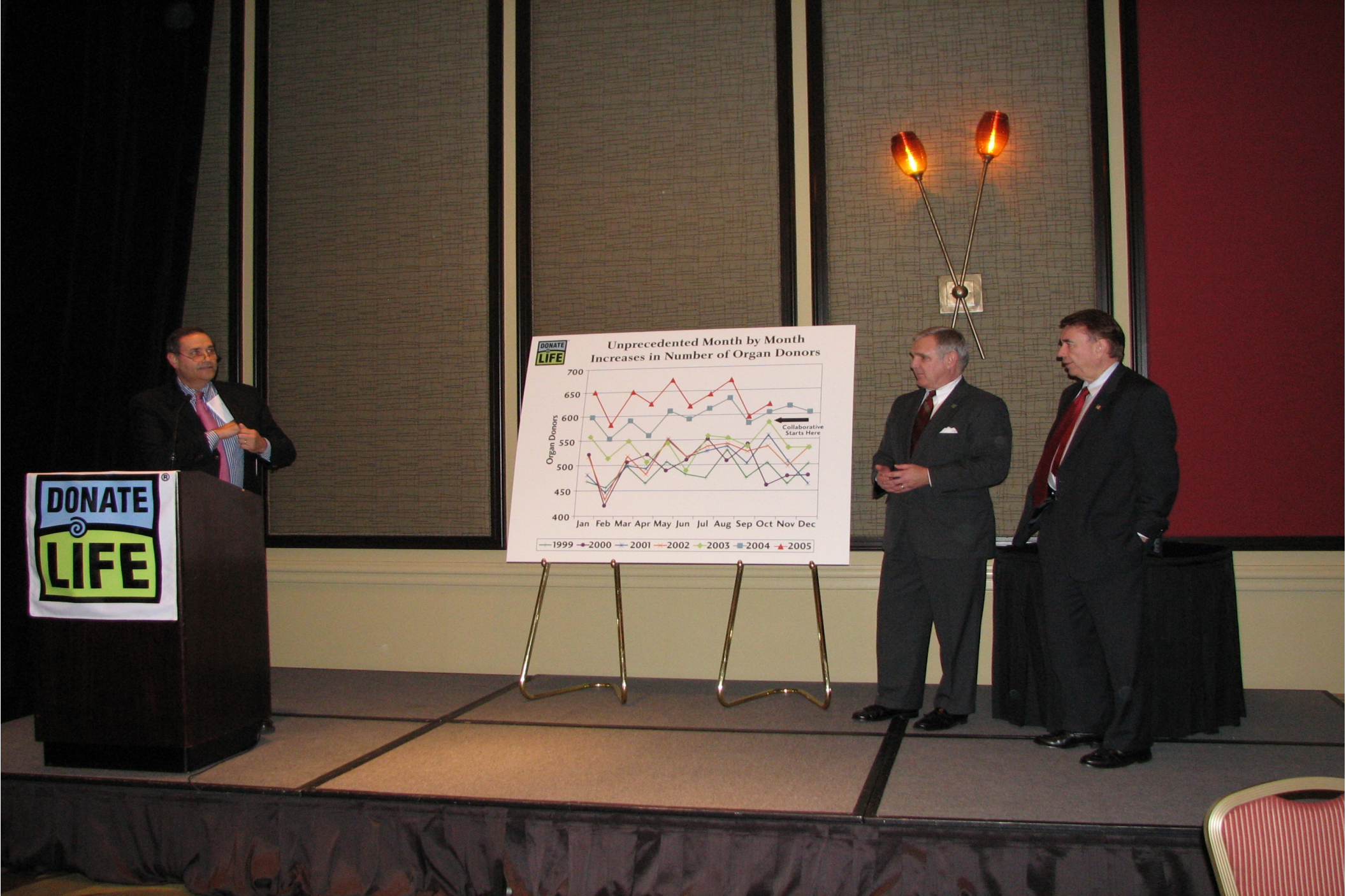
- **Transplant candidates**
  - Medical urgency status
  - Clinical data
- **Donor/recipient matching**
  - Ranked list of potential recipients
  - Organ acceptance and refusals
- **Living Donors**
  - Pre-donation clinical data
  - Surgical & organ recovery data
  - Post-operative complications
- **Histocompatibility**
  - PRA testing
  - HLA typing, methods & sources
  - Crossmatching

Data is collected for the following:

- **Deceased donors**
  - Procurement and consent
  - Terminal lab data
  - Serologies
  - Donor management prior to cross clamp
- **Transplant recipients**
  - Patient and graft status
  - Clinical information
  - Malignancies
  - Immunosuppressive treatments

Who Uses OPTN Data?

- OPTN Membership
- Transplant Patients
- HRSA/CMS/ESRD Networks
- Other government agencies
- Professional Organizations
- Media
- Health Care Industry
- Students


DONATE LIFE
Unprecedented Month by Month
Increases in Number of Organ Donors
Organ Donors
700
650
600
550
500
450
400
Collaborative Starts Here
Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec
1999 2000 2001 2002 2003 2004 2005
DONATE LIFE

Comment: A commenter who supports the use of organ donation potential in the CMS outcome measures said that population demographics should be considered along with potential. For example, the commenter pointed out that in some areas, donors are older and that even "standard criteria" donors may be sicker than in other parts of the country.

Response: HRSA has advised us that the OPTN and SRTR are considering whether certain conditions and circumstances that may affect the health of standard criteria donors (SCDs) should be factored into the measures used to evaluate OPO performance. If the OPTN and SRTR make this change, we will consider whether we should incorporate it into our outcome measures through future rulemaking.

criteria for an "eligible death.")

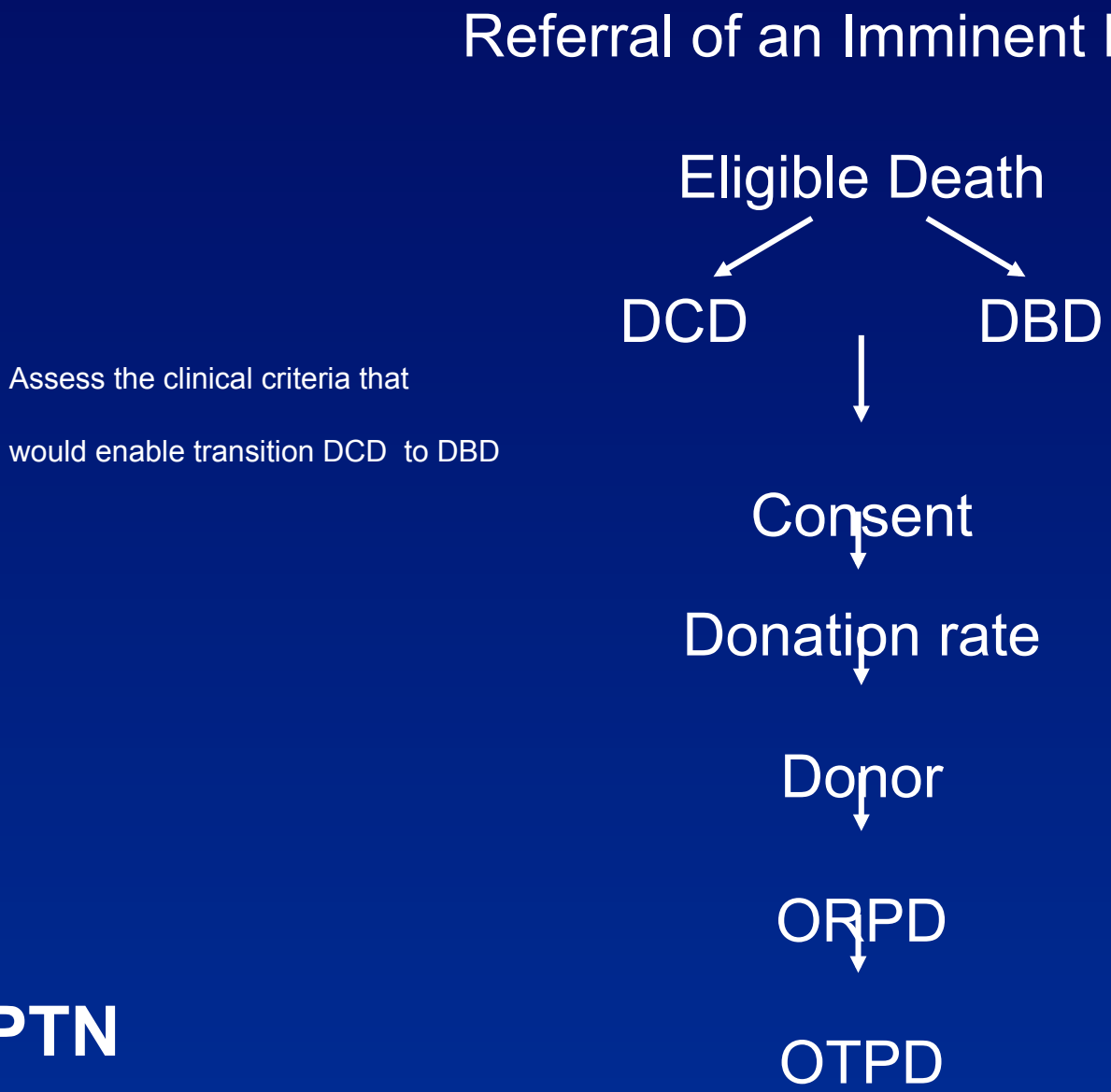
Comment: Some commenters drew attention to the fact that a donation rate outcome measure would be based on self-reported hospital referral data. (In both the proposed rule and in this final rule, the first outcome measure is a donation rate, that is, the number of actual organ donors ("eligible donors" in this final rule) as a percentage of the number of potential organ donors ("eligible deaths" in this final rule). The number of eligible deaths is a subset of the deaths that hospitals report to their designated OPOs. Hospitals are required to report all deaths and imminent deaths to OPOs under § 486.345.) Commenters said that if an OPO does not develop good working relationships with its hospitals, the hospitals likely will not refer all deaths or imminent

they submit to the OPTN are valid.

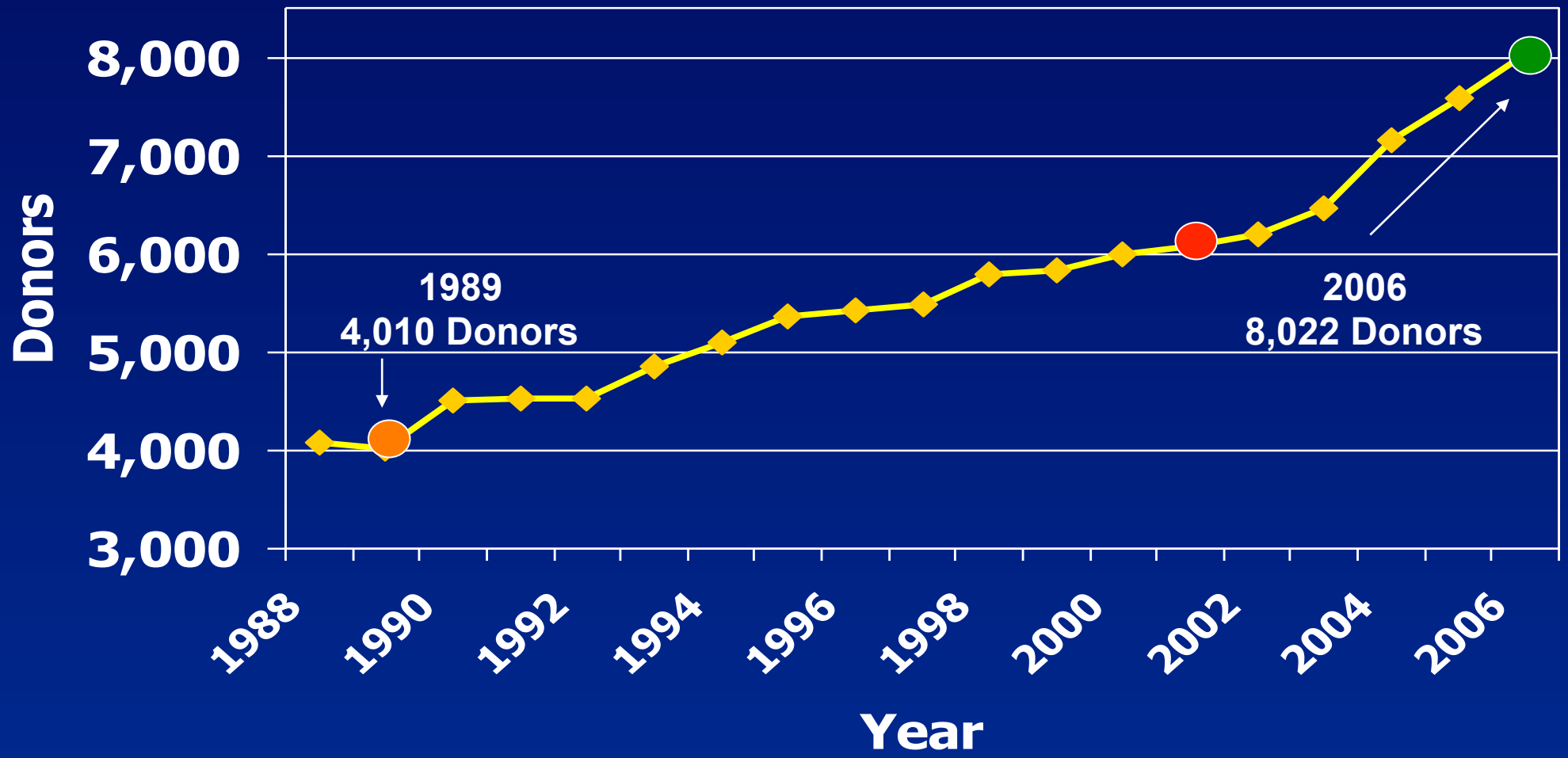
Comment: Commenters also said that the outcome measures for kidneys and extra-renal organs procured are subject to manipulation by OPOs that recover organs that can not be transplanted, simply to increase their procurement rate.

Response: We consider a "donor" to be a deceased individual from whom at least one vascularized organ is removed for the purpose of transplantation. Thus, data on the number of donors, as well as the number of organs recovered, are subject to manipulation by an OPO that recovers an organ that is not suitable for transplantation, solely for the purpose of increasing its performance numbers. However, this final rule includes a measure that can not be manipulated—organs transplanted per donor. (See

Algorithm of Deceased Donation



All Deceased US Donors by Year



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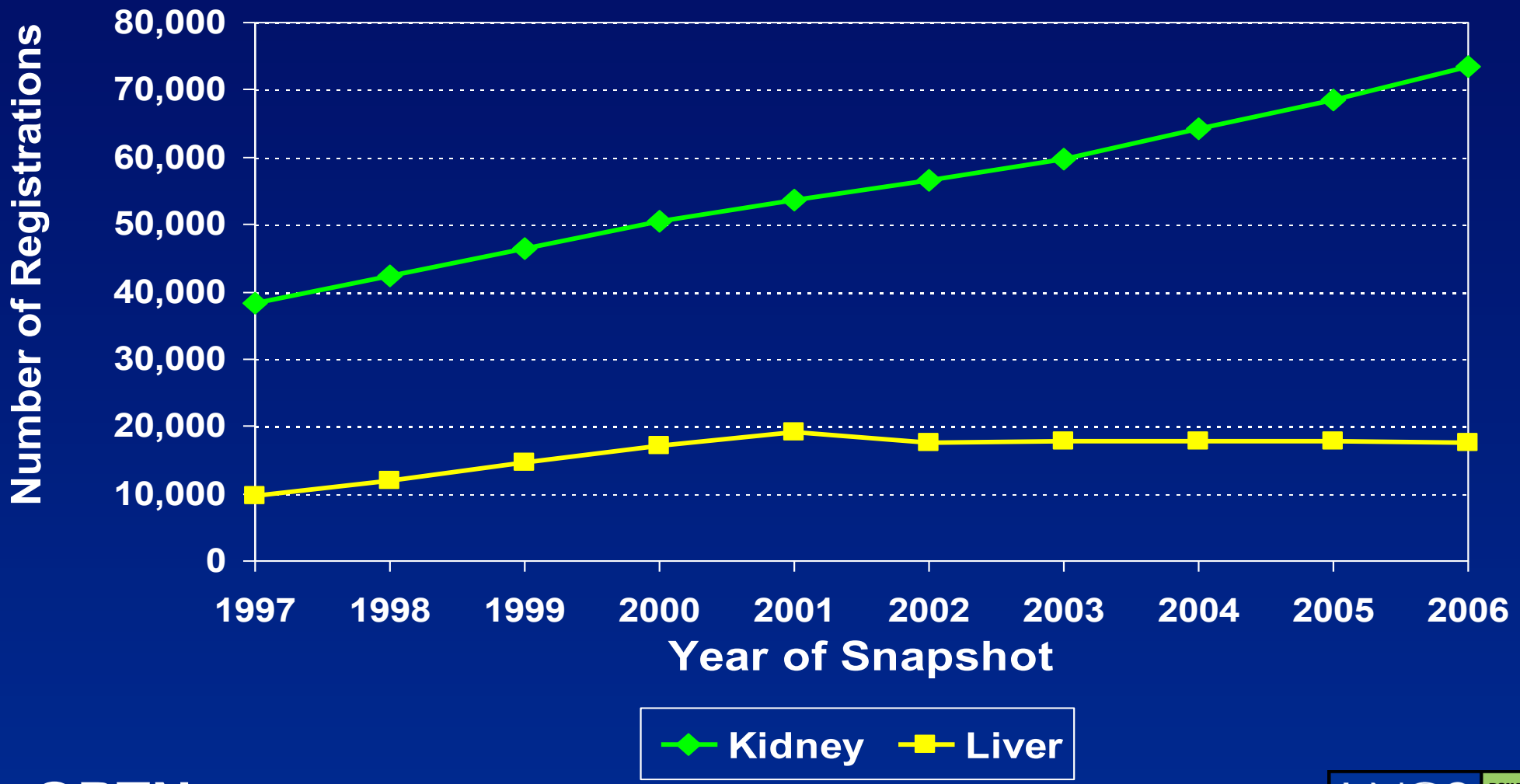
U.S. Waiting List Registrations 1997-2006



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COMPARISON OF MORTALITY IN ALL PATIENTS ON DIALYSIS, PATIENTS ON DIALYSIS AWAITING TRANSPLANTATION, AND RECIPIENTS OF A FIRST CADAVERIC TRANSPLANT

ROBERT A. WOLFE, PH.D., VALARIE B. ASHBY, M.A., EDGAR L. MILFORD, M.D., AKINLOLU O. OJO, M.D., PH.D., ROBERT E. ETTENGER, M.D., LAWRENCE Y.C. AGODOA, M.D., PHILIP J. HELD, PH.D., AND FRIEDRICH K. PORT, M.D.

. OUTCOME AMONG RECIPIENTS OF FIRST CADAVERIC TRANSPLANTS, ACCORDING TO CHARACTERISTICS AT THE TIME OF INITIAL PLACEMENT ON THE WAITING LIST, 1991–1997.*

GROUP	RELATIVE RISK 18 MO AFTER TRANSPLANTATION (95% CI)†	P VALUE	TIME AT WHICH RISK OF DEATH EQUALS THAT IN REFERENCE GROUP	TIME AT WHICH LIKELIHOOD OF SURVIVAL EQUALS THAT IN REFERENCE GROUP	PROJECTED YEARS OF LIFE (IN REFERENCE GROUP) WITHOUT TRANSPLANTATION†‡	PROJECTED YEARS OF LIFE WITH TRANSPLANTATION‡
			days after transplantation			
All recipients of first cadaveric transplants	0.32 (0.30–0.35)	<0.001	106	244	10	20
Age						
0–19 yr	0.33 (0.12–0.87)	0.03	3	5	26	39
20–39 yr	0.24 (0.20–0.29)	<0.001	11	57	14	31
40–59 yr	0.33 (0.29–0.37)	<0.001	95	251	11	22
60–74 yr	0.39 (0.33–0.47)	<0.001	148	369	6	10
Age and diabetes status						
20–39 yr, no diabetes	0.38 (0.28–0.50)	<0.001	14	220	20	31
20–39 yr, diabetes	0.18 (0.14–0.23)	<0.001	10	35	8	25
40–59 yr, no diabetes	0.38 (0.33–0.43)	<0.001	126	356	12	19
40–59 yr, diabetes	0.27 (0.23–0.32)	<0.001	66	181	8	22
60–74 yr, no diabetes	0.37 (0.30–0.46)	<0.001	159	442	7	12
60–74 yr, diabetes	0.46 (0.34–0.61)	<0.001	89	247	5	8

Life Years From Transplantation From A Donated Organ

- LYFT is the number of extra years of life that a candidate could expect to live with that donated organ compared to without a transplant.
- Example: Based on patient and donor characteristics the remaining lifetime might be estimated as:
  - 15 years with this transplant and
  - 5 years without transplant.
  - LYFT = 10 = 15 – 5 = Ten extra years of life

The Kidney Allocation Review Subcommittee (KARS)

Mark D. Stegall, Alan Leichtman, Peter Stock, Kenneth Andreoni, Mary S. Leffel, Dori Segev, Trent Tipple, Winifred Williams, Kevin O'Connor, Michael Shapiro, James Wynnj, Keith P. McCullough and Robert A. Wolfe

The schema seeks to balance improvements in the utility of the system with providing equitable transplant opportunities by employing three major components:

1) a continuous ranking schema for donors (termed the donor profile index, DPI);
2) 2) a continuous method of assigning priority points using objective medical criteria (termed life years from transplant, LYFT);
3) 3) a component of waiting time (defined as time elapsed from the start of dialysis) that allows candidates to move up the list.

KPSAM simulations current schema and possible alternative schemas.

The table lists the results of the current schema in 2003.

The major outputs are the total lifespan of all transplanted patients compared to remaining on dialysis (Δ Lifespan), total years of graft survival (Δ Graft years), LYFT (life years from transplant) = Recipient survival with transplant – survival remaining on dialysis (dialysis years discounted as 0.8 versus transplant years counted as 1.0).

	Current Schema	LYFT Alone	LYFT +0.5 Time	LYFT Time by Cont. DPI	LYFT Time by Cont.DPI^2	Age Matching	Quintile LYFT vs DPI
Δ Lifespan	Ref *108,044**	35,018	28,252	20,505	27,912	19,659	493
Δ Graft years	Ref *73,318*	13,105	9,279	6,191	9,140	8,322	2,433
ΔLYFT	Ref *48,424*	11,346	9,718	7,079	9,294	7,871	198

	Current Schema	LYFT Alone	LYFT +0.5 Time	LYFT Time by Cont. DPI	LYFT Time by Cont.DPI^2	Age Matching	Quintile LYFT vs DPI
Rec. African Am.%	32.5	33.0	36.3	36.7	35.1	34.9	35.3
Rec. Hispanic	13.5	14.8	14.6	14.5	14.7	14.0	13.8
Rec. Caucasian	47.4	44.7	42.1	41.9	43.1	45.3	44.0
Rec. Other	6.5	7.5	7.0	6.8	7.0	6.6	6.9
Rec. <18 years	6.7	7.2	7.2	7.1	7.1	7.4	7.0
Rec. 18-34 years	12.9	33.7	31.4	27	31.9	21.2	10.5
Rec. 35-49 years	30.5	31	32.2	32.2	30.9	35.3	27.6
Rec. 50-64	37.8	21.9	22.9	26.5	23.4	30.8	41.2
Rec. 65+	12.2	6.2	6.3	7.2	6.3	5.3	13.6