

*The National
Academies of*

SCIENCES
ENGINEERING
MEDICINE

THE COMMITTEE ON A FAIRER AND MORE EQUITABLE, COST-EFFECTIVE, AND TRANSPARENT
SYSTEM OF DONOR ORGAN PROCUREMENT, ALLOCATION AND DISTRIBUTION: PUBLIC WORKSHOP
FEBRUARY 4 & 5, 2021

SESSION II: THE U.S. ORGAN PROCUREMENT SYSTEM

Overview of the Organ Procurement System

A Historical Perspective

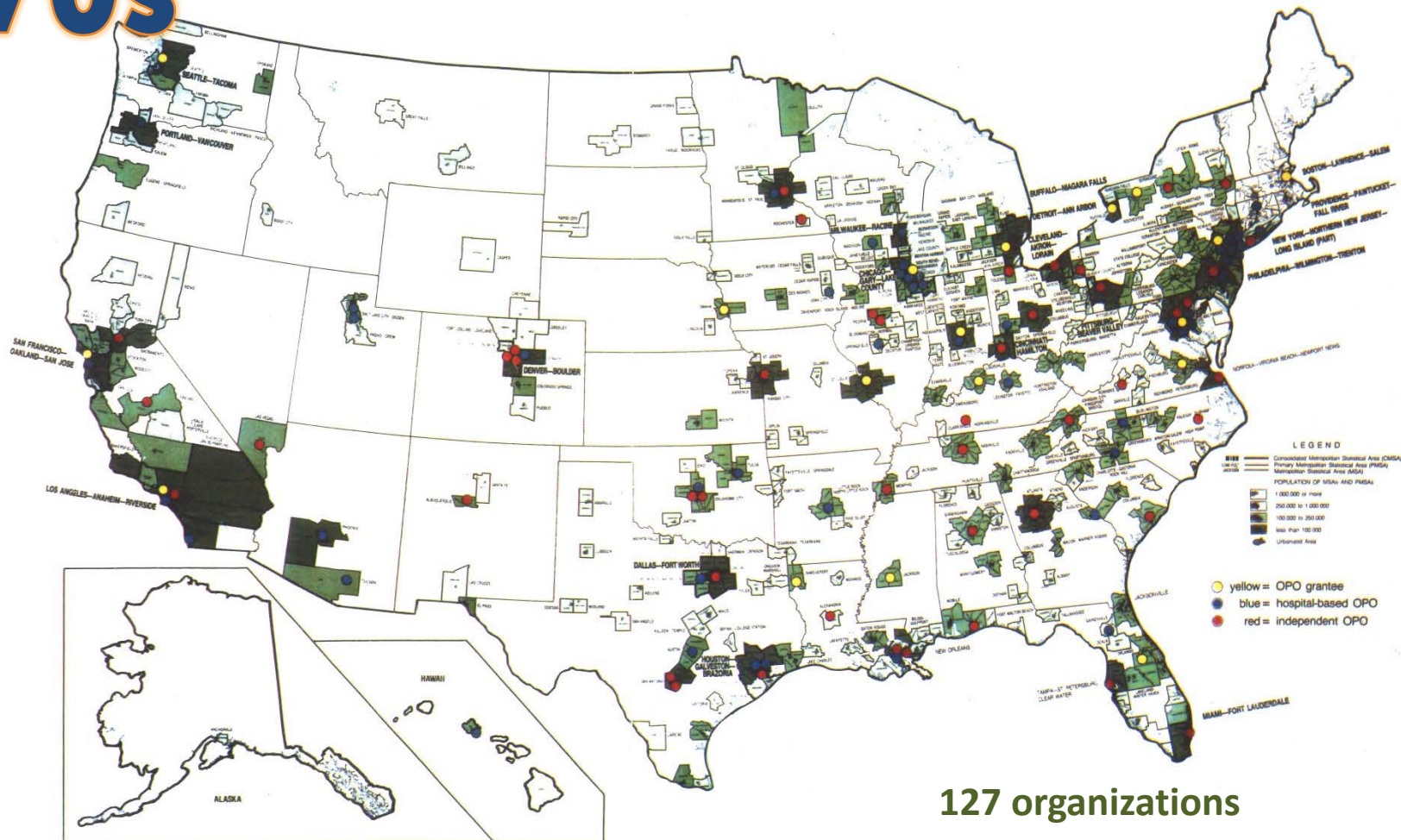
Presented by:

Howard M. Nathan
President and CEO
Gift of Life Donor Program



1970s

Distribution of Organ Procurement Organizations in the United States

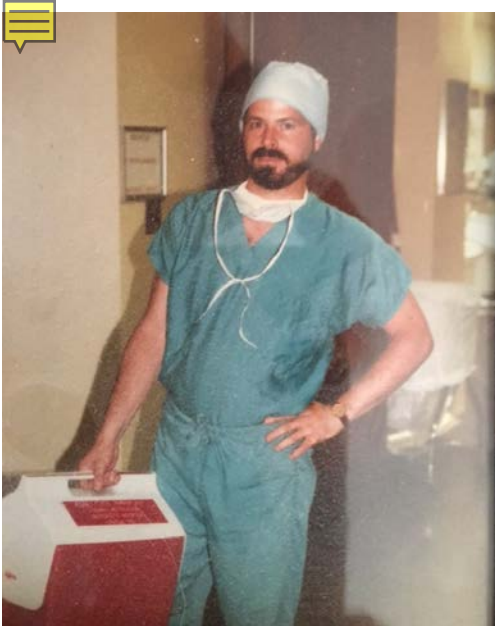


127 organizations

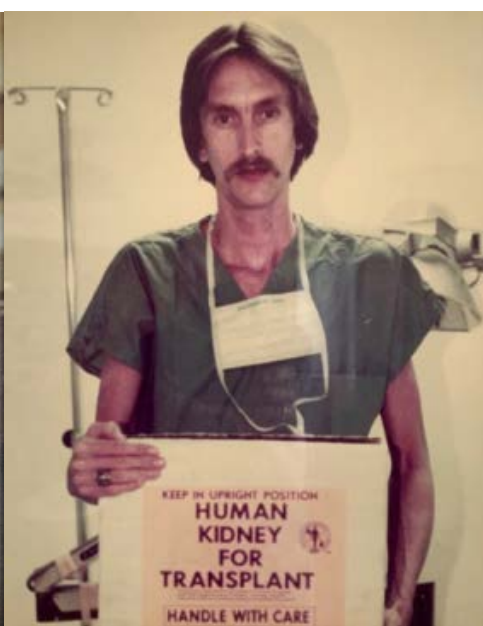
Early Regional Procurement Programs

<u>PROGRAM</u>	<u>ESTABLISHED</u>
Interhospital Organ Bank (New England Organ Bank/NEDS)	1968
Southeast Organ Procurement Foundation (SEOPF)	1969
Organ Procurement Organization of Michigan (Gift of Life Michigan)	1971
New York/New Jersey Regional*	1972
Midwest Organ Bank (Midwest Transplant Network)	1973
ROPA of Los Angeles (now One Legacy)	1973
Illinois Transplant Society	1973
Delaware Valley Transplant Program (Gift of Life Donor Program)	1974
Dialysis Clinics Inc. Tennessee Donor Services	1975

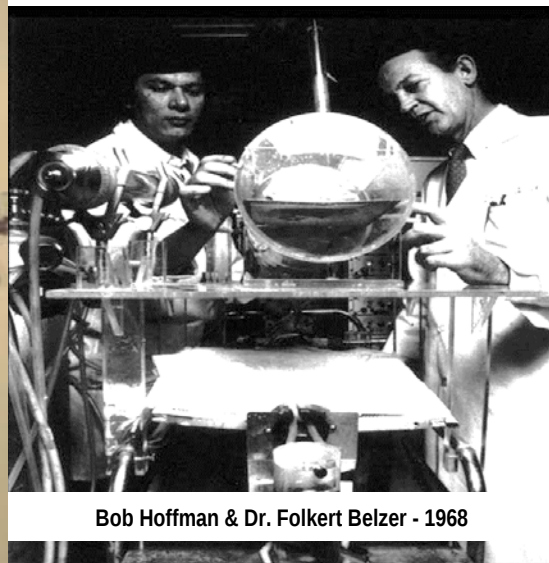
**Disbanded in 1978*



Howard Nathan - 1978



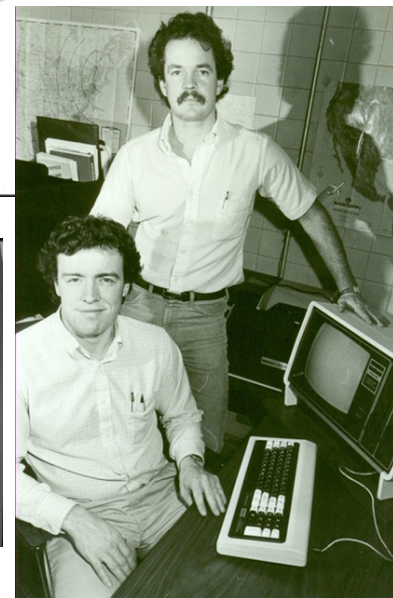
Kidney Transport, Charles Bearden - 1979



Bob Hoffman & Dr. Folkert Belzer - 1968



Faye Davis - 1981



Bruce Zalneraitis & Kevin O'Connor
1984



Bill Anderson - 1975



Les Olsen - 1971

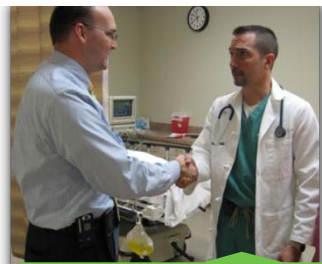


Mike Phillips, 1975

Transplant Coordinator Responsibilities



Referral Triage



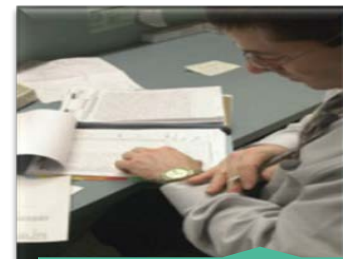
On-site response to hospital



Donor Evaluation for Suitability



Family Discussion/ Authorization



Donor Management / Testing



Allocation



Coordination of OR / Transplant Recovery Teams



Recovery



Transplant



Hospital Development (Case Follow Up to Families and HCT)



1969

- **Southeastern Organ Procurement Foundation (SEOPF)**
Kidney sharing among 50+ kidney transplant centers
 - Founded by David Hume, Medical College of Virginia and D. Bernard Amos, Duke University, NC
- **1977 - Developed UNOS computer-based system for matching kidneys**
- **This was the pre-cursor to the UNOS contract in 1986**

Old Allocation Process

NATCO 24-ALERT System and Its Role in Extrarenal Organ Sharing



NATCO 24-ALERT MATCHING SYSTEM

September 1982 - August 1986

1204	Liver
1168	Hearts
65	Heart/Lungs
4	Lungs
122	Tissue

215 lbs

MCV status ~~extremely urgent~~
no x-match
fly 1000 mi
(804) 786-0465

Metro Transplant ~~extremely~~
no x-match
fly 500 mi
(574) 527-0047

NRDPA extremely urgent
x-match - yes
fly 1000 mi
(615) 748-1155

St Lukes WI status 1
x-match - no
fly 1500 mi
(414) 649-3700

Abbott Northwestern Minn, Minn. Status 1
no x-match
fly 1500 mi
(612) 874-5700

THI status 1 link
no x-match
fly 1000 mi
(713) 791-4146

MCU status 2
x-match yes

Ed
HAG

Heart List

From 24-ALERT

1987 – HCFA OPO Designations (per NOTA and Task Force Report)

- 78 OPOs with designated service areas (DSA) by MSSA
- Consolidation within metro areas and some states
- No competition within a DSA
- OPO metrics established later (early 1990s)
 - Kidneys recovered and Transplanted/Million;
Donors/Million

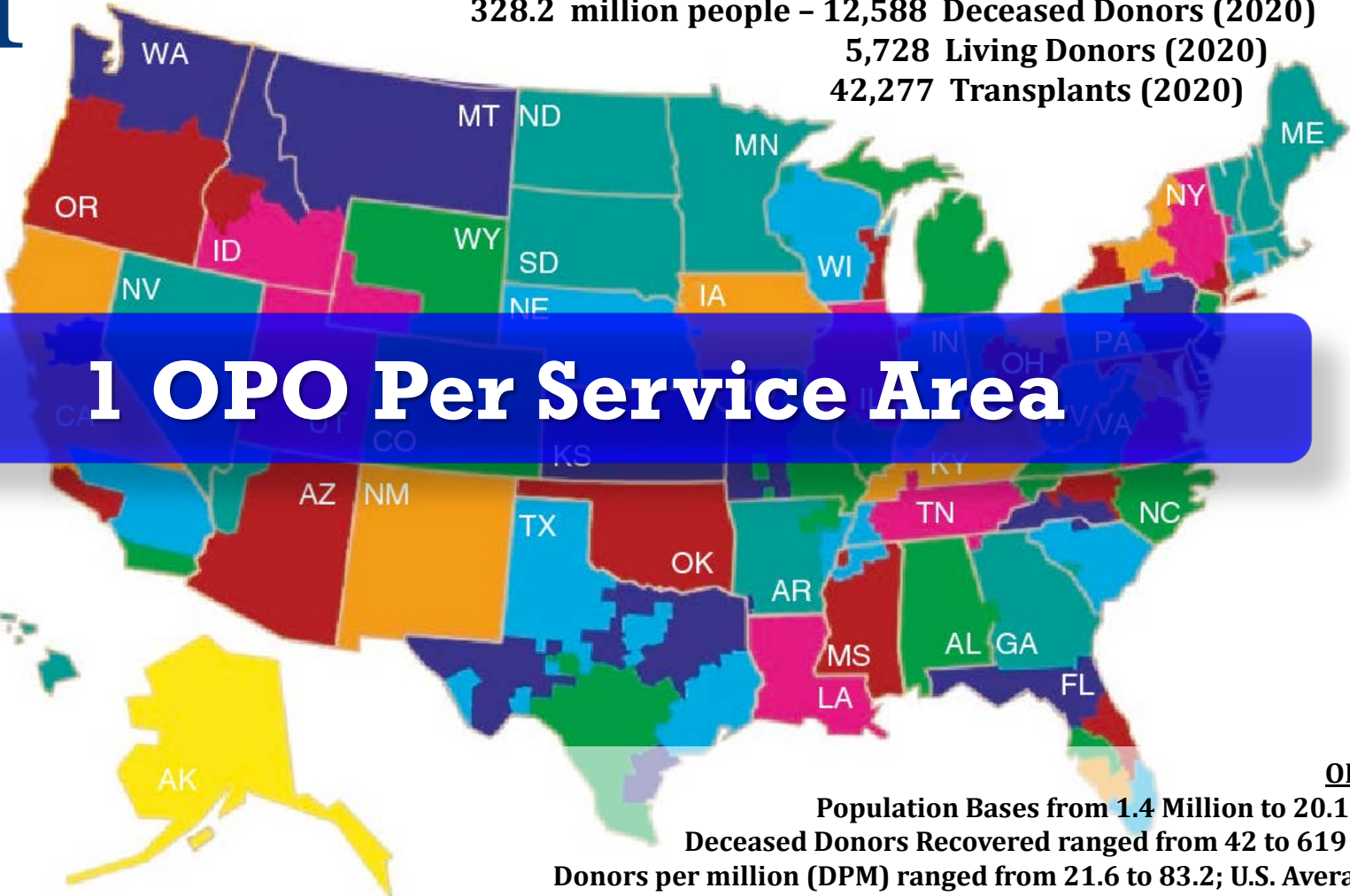
 **2021**

57 OPO Donation Service Areas in the U.S.

328.2 million people – 12,588 Deceased Donors (2020)

5,728 Living Donors (2020)

42,277 Transplants (2020)



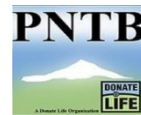
1 OPO Per Service Area

OPO Data

Population Bases from 1.4 Million to 20.1 Million

Deceased Donors Recovered ranged from 42 to 619 Donors

Donors per million (DPM) ranged from 21.6 to 83.2; U.S. Average 38.4



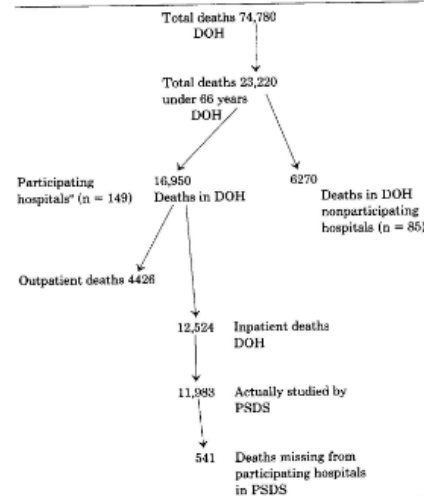
ESTIMATION AND CHARACTERIZATION OF THE POTENTIAL RENAL ORGAN DONOR POOL IN PENNSYLVANIA

REPORT OF THE PENNSYLVANIA STATEWIDE DONOR STUDY^{1,2}

HOWARD M. NATHAN,³ BRUCE E. JARRELL,⁴ BRIAN BROZNIK,⁵ ROB KOCHIK,⁶ BRIAN HAMILTON,⁶
SUSAN STUART,³ TED ACKROYD,⁷ AND MARIE NELL,⁷

Delaware Valley Transplant Program, Philadelphia; Thomas Jefferson University, Philadelphia; Pittsburgh Transplant Foundation, Pittsburgh; and Healthcare Research Affiliates, Harrisburg, Pennsylvania

TABLE 5. Summary of deaths in the State of Pennsylvania acute-care hospitals in 1987 as reported by the Department of Health (DOH, [Vital Statistics]) and the Pennsylvania Statewide Donor Study (PSDS)



* Participating and nonparticipating hospitals are those in or not in the PSDS.

TABLE 6. Characteristics of the Pennsylvania Statewide Donor Study of participating and nonparticipating centers

	Participating centers	Nonparticipating centers
Number	149	85
Location		
Large urban region	71	36
Small city	52	24
Rural area	25	19
Unclassified	1	6
Type of educational facility		
None	63	37
University	6	2
University-affiliated or training program	80	40
Intermediate or major trauma center designation	18	4
Transplant center	10	1
Actual donors produced during 1987	147	50

The Pennsylvania Statewide Donor Study evaluated deaths under the age of 66 occurring in 149 participating hospitals in 1987. After elimination of 6146 patients from 11,983 based upon ICD-9 code criteria, an on-site medical record review was performed on 5603 patients. Each patient was assessed for organ donor suitability based upon brain death and medical suitability criteria—and, after a series of eliminations, 453 patients were found to have a moderate or higher potential as acceptable organ donors. An **estimated potential donor rate was placed between 38.3 and 55.2 donors per million population per year, depending upon the stringency of organ donor criteria.** Educational efforts targeted at physicians, patient's families and transplant surgeons will be necessary, however, to attain this maximal rate.

Since 1986, the number of cadaver kidney transplants performed in the United States has plateaued at approximately 7000 annually, due to limitations of the number of cadaver donations (1). The waiting list of patients, however, continues to grow. The United Network for Organ Sharing (UNOS) reported 17,162 patients waiting for kidneys in April of 1990, whereas there were 9571 patients waiting three years previously, representing an increase of 80% (2).

It is not known what the potential donor pool is in the United States. A study to determine the number of potential donors was undertaken by the Center for Disease Control in 1975. This project reported an annual potential donor rate ranging from a minimum of 110 kidneys/million population to a maximum of 232 kidneys/million. They performed retrospective medical record reviews in hospitals in three states utilizing two types of donor medical criteria: center-specific (a more conservative approach) and broad-based intercenter criteria (a more liberal approach) (3). The Task Force on Organ Transplantation estimated the national potential donor pool at approximately 20,000 annually, with a range of 17,000 and 26,000

potential donors, based on this study and the results of other similar studies (4).

Thus the Pennsylvania Statewide Donor Study (PSDS) was conceived and undertaken to determine the number of medically suitable potential cadaver donors in this state by performing a detailed retrospective medical record review of 1987 in-hospital deaths. The study included criteria for brain death potential, as well as organ-specific donor medical criteria. This characterization of the potential donor pool (e.g., age, sex, race, cause of death, ICD-9-CM codes, hospital and medical care unit) when compared both with actual donors and potential donors not identified as such might allow improvement in donor recognition schemes directed toward the goal of increasing donors. This could be achieved by creating focused educational programs targeted toward health-care professionals in hospitals identified with the largest "donor gaps."

MATERIALS AND METHODS

In 1987 Pennsylvania had eleven organ transplant centers and two organ procurement organizations to serve the state's 234 acute care hospitals and twelve million people. The potential for cadaver renal donors in Pennsylvania during this period was evaluated using a stepwise evaluation of deaths throughout the entire state. Each of the 234 hospitals was asked to participate in the study.

Step I: abstract review and initial screen. Participating hospitals submitted an abstract of each death occurring during 1987. This patient abstract contained the following data: patient and hospital identification number, age, sex, race, insurance coverage, medical care unit, ICD-9-CM diagnosis code (first through fifth), E, M, and V codes, primary and secondary procedure codes, and date of death. These data were screened by review of the abstract. Patients over age 65 or fitting ICD-9-CM diagnosis codes shown in Table 1 were eliminated from further study.

For comparison, the State of Pennsylvania Department of Health submitted vital statistics for the state during 1987. These data included hospital identification number, age, death codes, and location of death (inpatient, outpatient, DOA, etc.).

Step II: on-site medical record review. Patients remaining in the database after the initial screen were subject to more intensive review. On-site medical record reviews were performed by three experienced research assistants, one in each region of the state. The research assistants evaluated the patient for signs or symptoms of neurological dysfunction or brain death, and eliminated the patient from further study if none was present. If one or more neurologic signs or symptoms was present, the patient was assessed to determine if cardiovascular death occurred prior to the development of brain death. If cardiovascular death occurred first and, in the opinion of the reviewer there were inadequate circumstances to allow possible donation (such as unsuccessful cardiopulmonary resuscitation), the patient was eliminated

¹ Presented at the 16th Annual Meeting of the American Society of Transplant Surgeons, May 30–June 1, 1990, Chicago, IL.

² This work was supported by Department of Health and Human Services, Division of Organ Transplantation, OPO Grant 10TH-000-8201.

³ Address correspondence to: Howard M. Nathan, B.S., Delaware Valley Transplant Program, 2401 Walnut St., Philadelphia, PA 19103.

⁴ Thomas Jefferson University.

⁵ Pittsburgh Transplant Foundation.

⁶ Delaware Valley Transplant Program.

⁷ Healthcare Research Affiliates.

1991

Estimated Potential Organ Donor Rate in PA: 38.3 – 55.2 DPM

Potential of 13,000 brain dead kidney donors (under age 66) extrapolated to U.S. population

Pennsylvania Act 102

1994

HOSPITALS

- Routine Referral of ALL patient deaths to OPO
- Medical Suitability of Potential donors determined by OPO
- Authorization Requests by OPO staff or “designated requestors”
- Medical Record Reviews with \$500 fine for missed referrals

DRIVER'S LICENSE REGISTRY

- Established donor registry in DMV
- 24-hour OPO-only access
- Donor Awareness Trust Fund established (public education, schools, funeral expenses, etc.)





PA ACT 102 of 1994

The Philadelphia Inquirer ■ Monday, March 16, 1998

Model program for finding organ donors

Penna. law credited with increasing donations is the gauge for a national effort.

By Stacey Burling
INQUIRER STAFF WRITER

A Pennsylvania law credited with greatly increasing organ donations here is now serving as a national model as the country tries to make a dent in the huge waiting lists for transplants.

The effort to make Pennsylvania's procedures national law, however, is running into opposition from the powerful American Hospital Association.

Pennsylvania's law, passed in 1994, had the backing of then-Gov. Robert P. Casey, a transplant recipient. It requires that, whenever anyone dies, the hospital must notify organ procurement organizations — agencies that

identify and distribute organs for transplants.

Only people trained in how to approach potential donor families are allowed make the request of the family. Since that law went into effect in 1995, organ donations have gone up in Pennsylvania by 40 percent while the number of organ donations in the country rose by only 6 percent.

Cornea transplants are now available in this area with virtually no wait.

Local transplant officials credit the law, known as the routine referral law, with this region's success. The region — eastern Pennsylvania, South Jersey and Delaware — had more organ donors last year than any other part of the country. In western Pennsylvania, an organ procurement organization spokesman said organ donations have not gone up

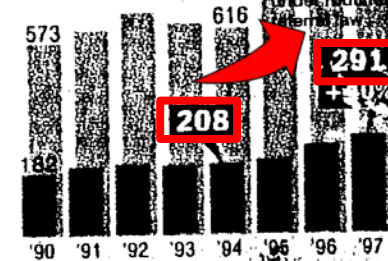
See **DONORS** on D3

Organ Donors

In the Delaware Valley Transplant Program

■ Number of organ donors
(Each donor can donate multiple organs.)

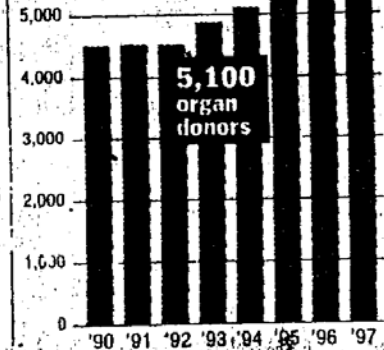
■ Number of organs transplanted



SOURCE: Delaware Valley Transplant Program

Nationwide

5,420
organ donors
+6%



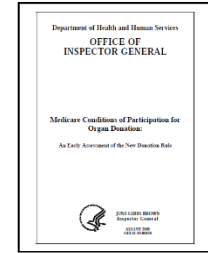
The Philadelphia Inquirer / STERLING CHEN

**43% increase of organ donors and transplants
over 3 years in Gift of Life region**

Revised Hospital Conditions of Participation For Hospitals Receiving Medicare Funding



*Routine Referral Process:
Mandates that **all deaths** must be referred to
OPOs by all hospitals in the United States
Effective date: August 21, 1998*



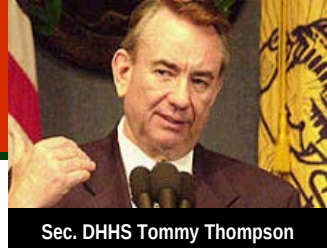
1998 CMS Conditions of Participation

- Hospitals must have a contract with OPOs
- All deaths must be reported to OPO via phone call (cardiac and ventilated patients)
- OPO personnel determine medical suitability of potential donors
- If the patient is medically suitable, the family must be given the option of donation
- Only OPO staff, or those trained and certified by the OPO, are to approach families



Organ Donation Breakthrough Collaborative From Best Practice to Common Practice

U.S. Department of Health and Human Services



Sec. DHHS Tommy Thompson

Two National Initiatives to Increase the Number of Available Transplantable Organs: 2003 – 2007

Breakthrough Collaborative for Organ Donation

- 🎯 Increase the number of actual organ donors as compared to eligible organ donors to **75%+ conversion rate**

- 🎯 **10% of potential donors to be DCD cases**

Breakthrough Collaborative for Transplantation

- 🎯 Increase average number of **organs transplanted per deceased donor to 3.75+**

Sharing of Best Practices that already work – “All teach, all learn”



OPOs



Donor
Hospitals

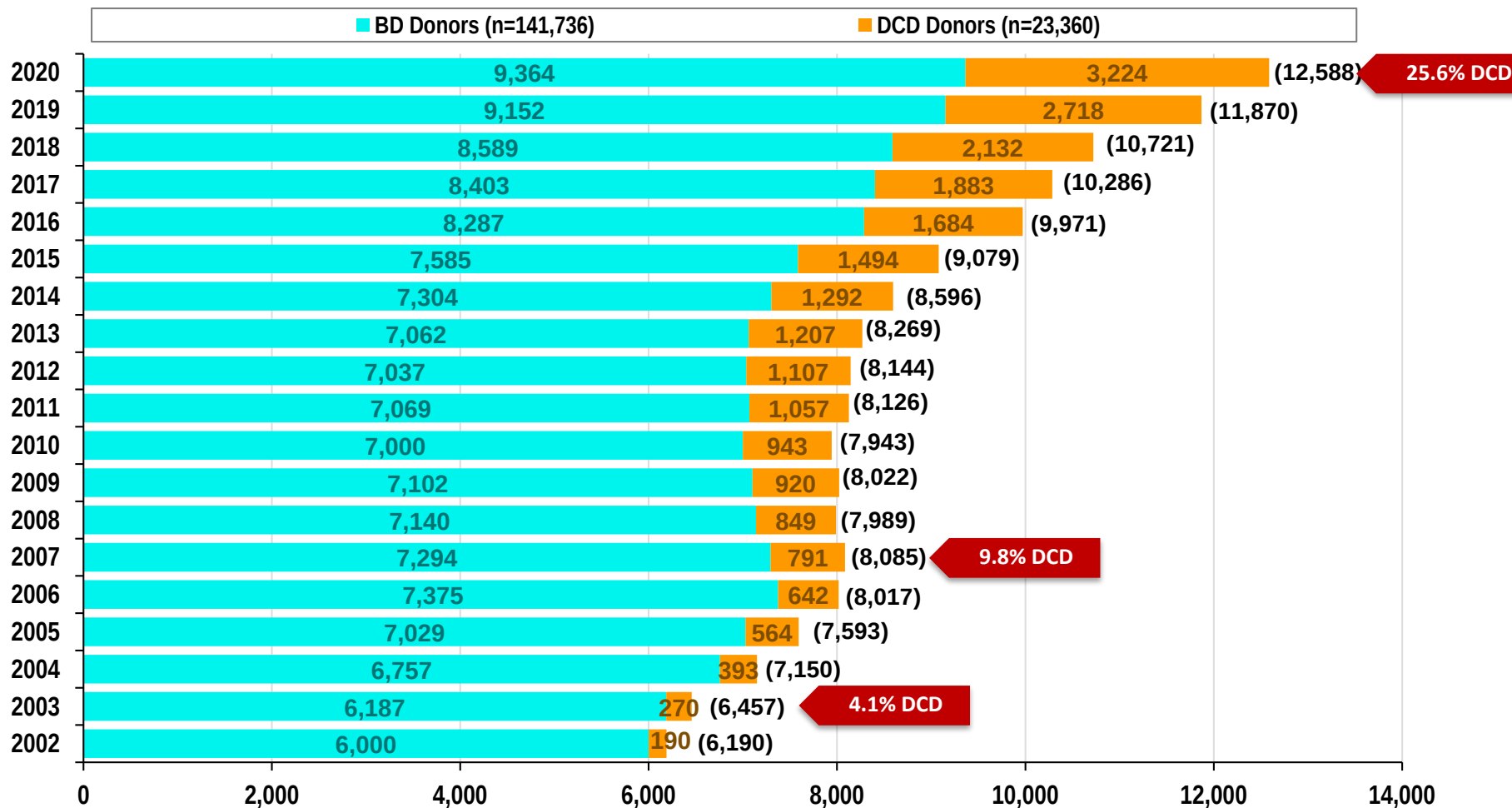
**Effective
Relationships
& Best
Practices**



Transplant
Centers

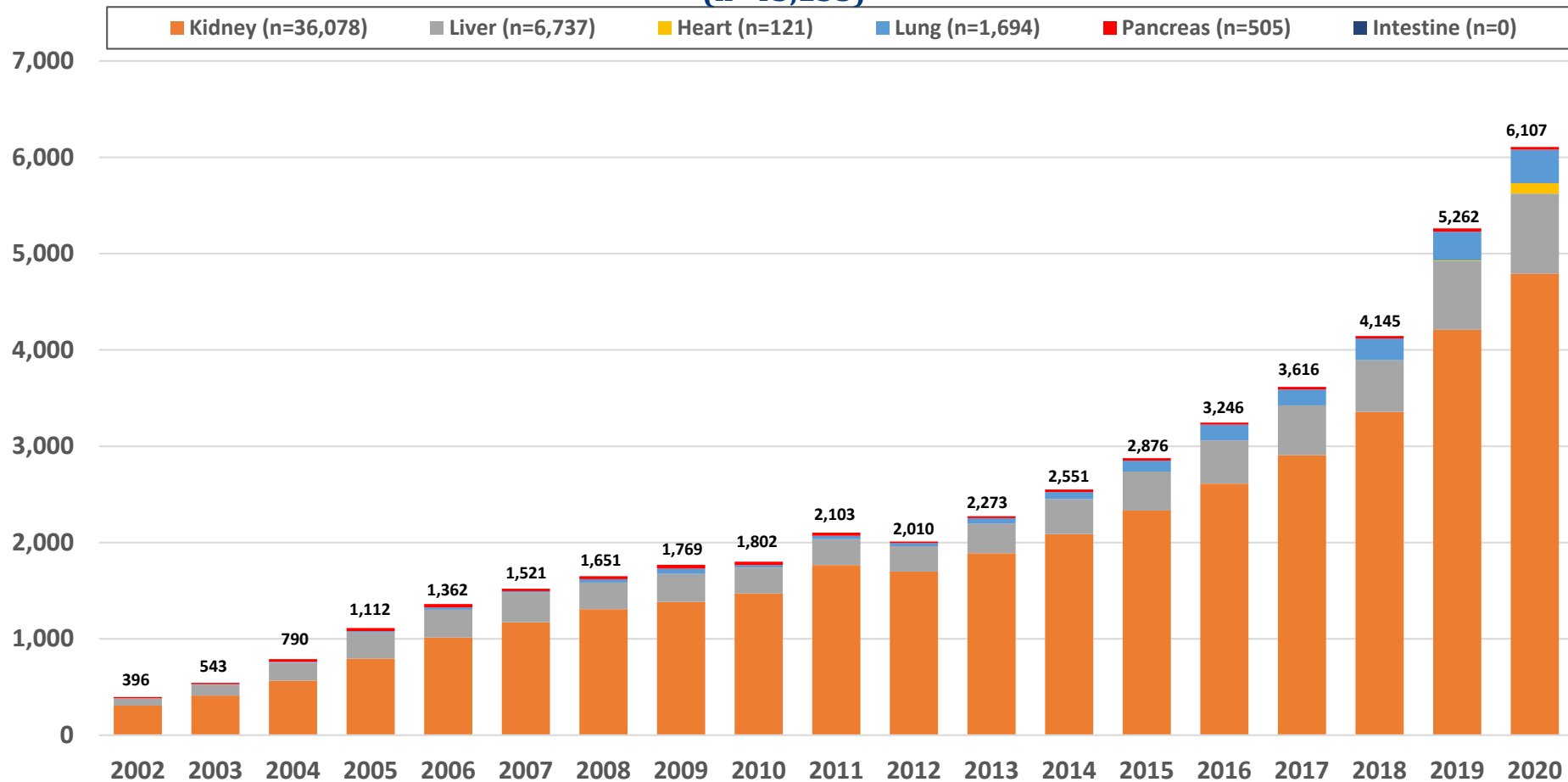


U.S. Organ Donor Experience – DBD & DCD Donors, 2002 – 2020



U.S. DCD Donor Organ Transplants, 2002 - 2020

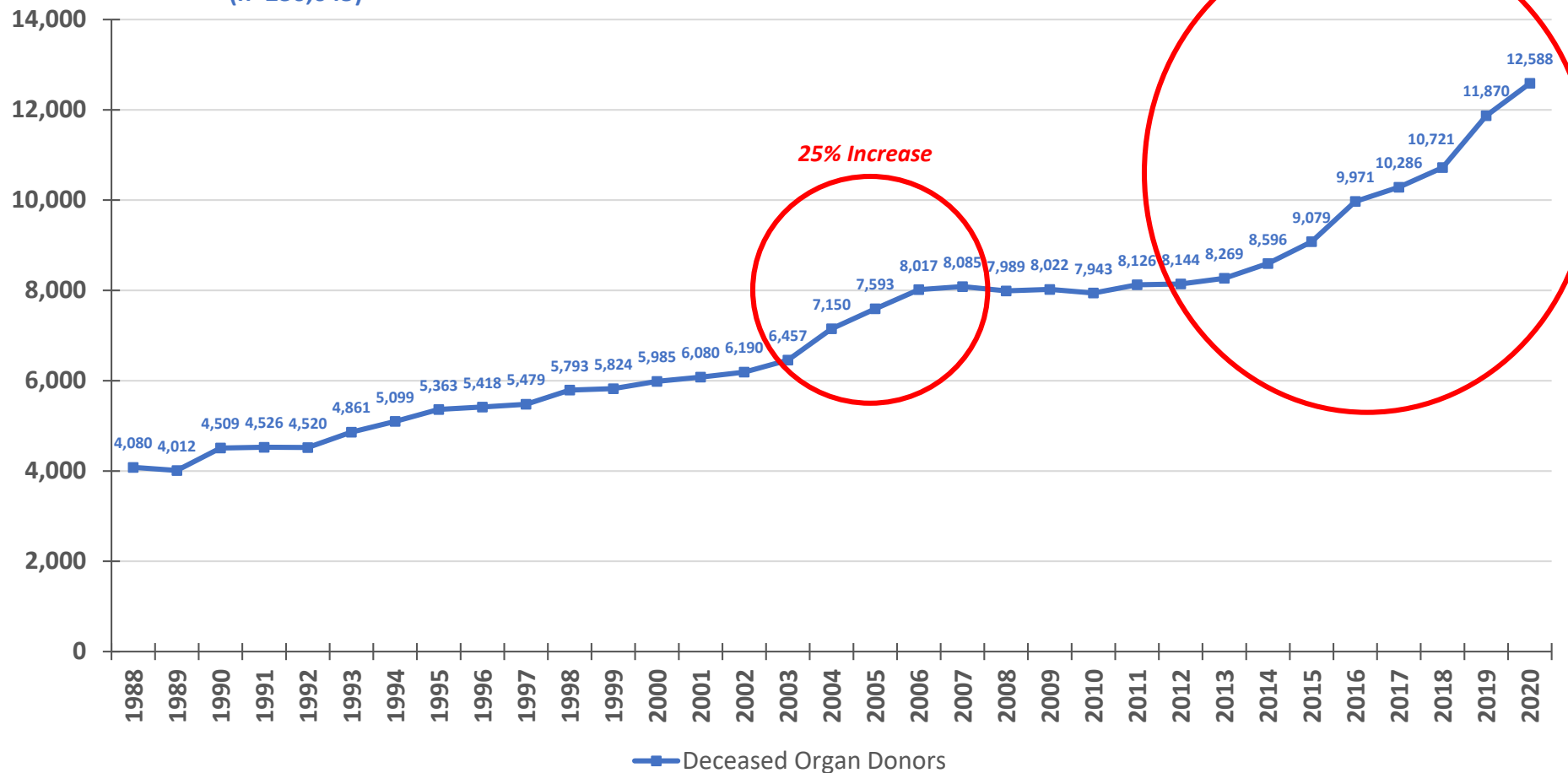
(n=45,135)



Source: OPTN data.

U.S. Deceased Organ Donors 1988 - 2020

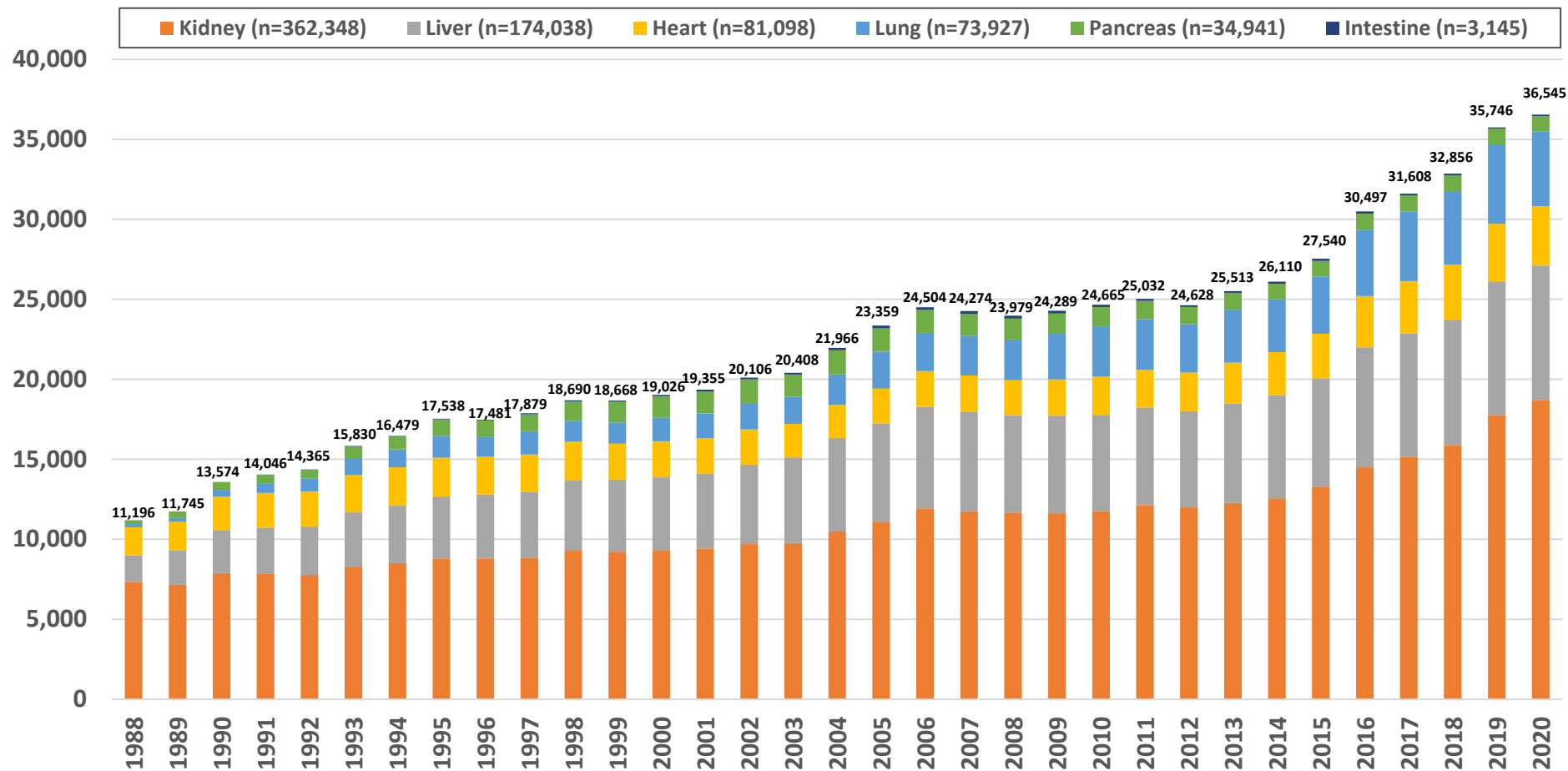
(n=236,645)



Source: OPTN data.

U.S. Deceased Organ Donor Transplants, 1988 - 2020

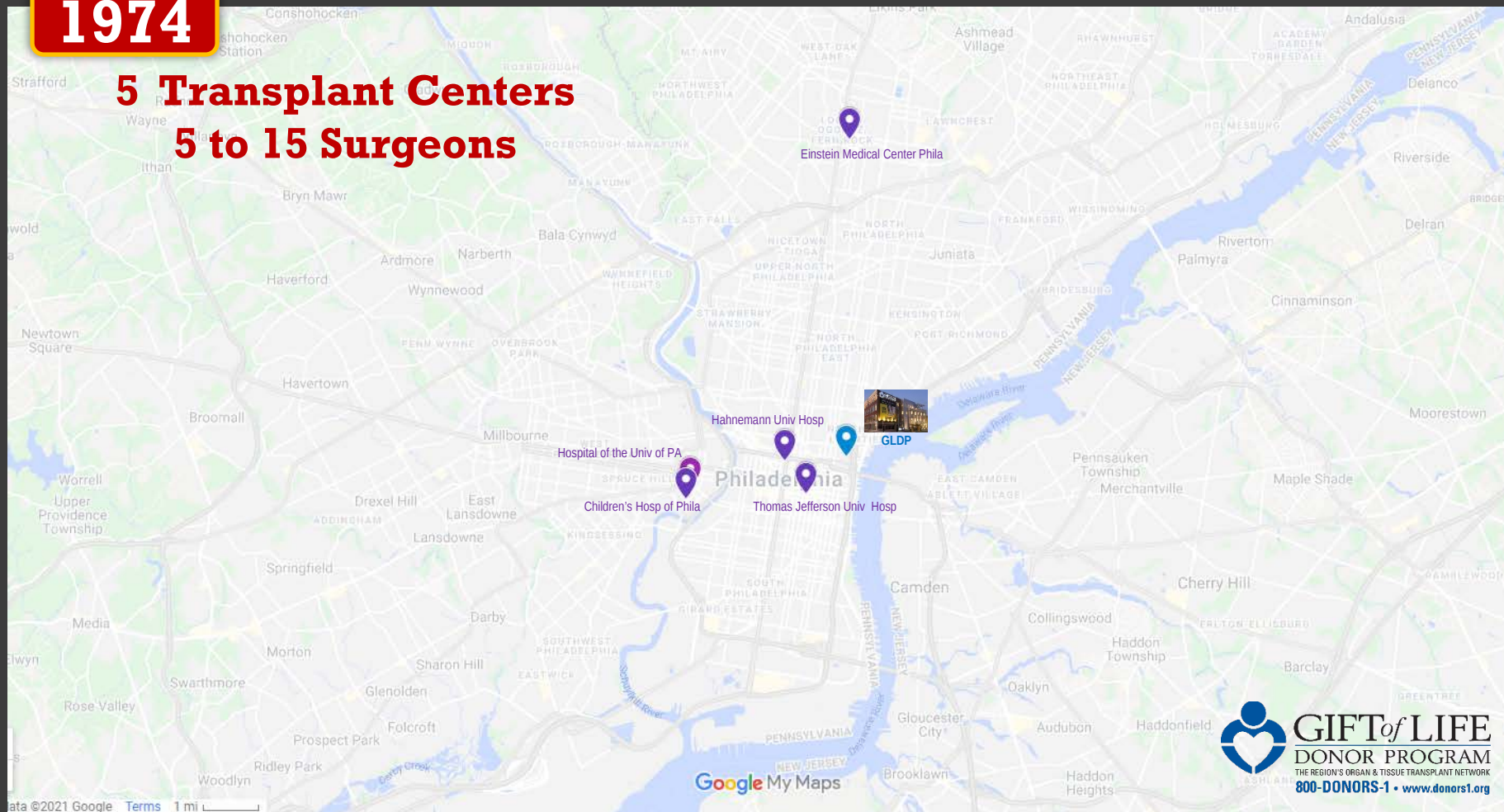
(n=729,497)



Source: OPTN data.

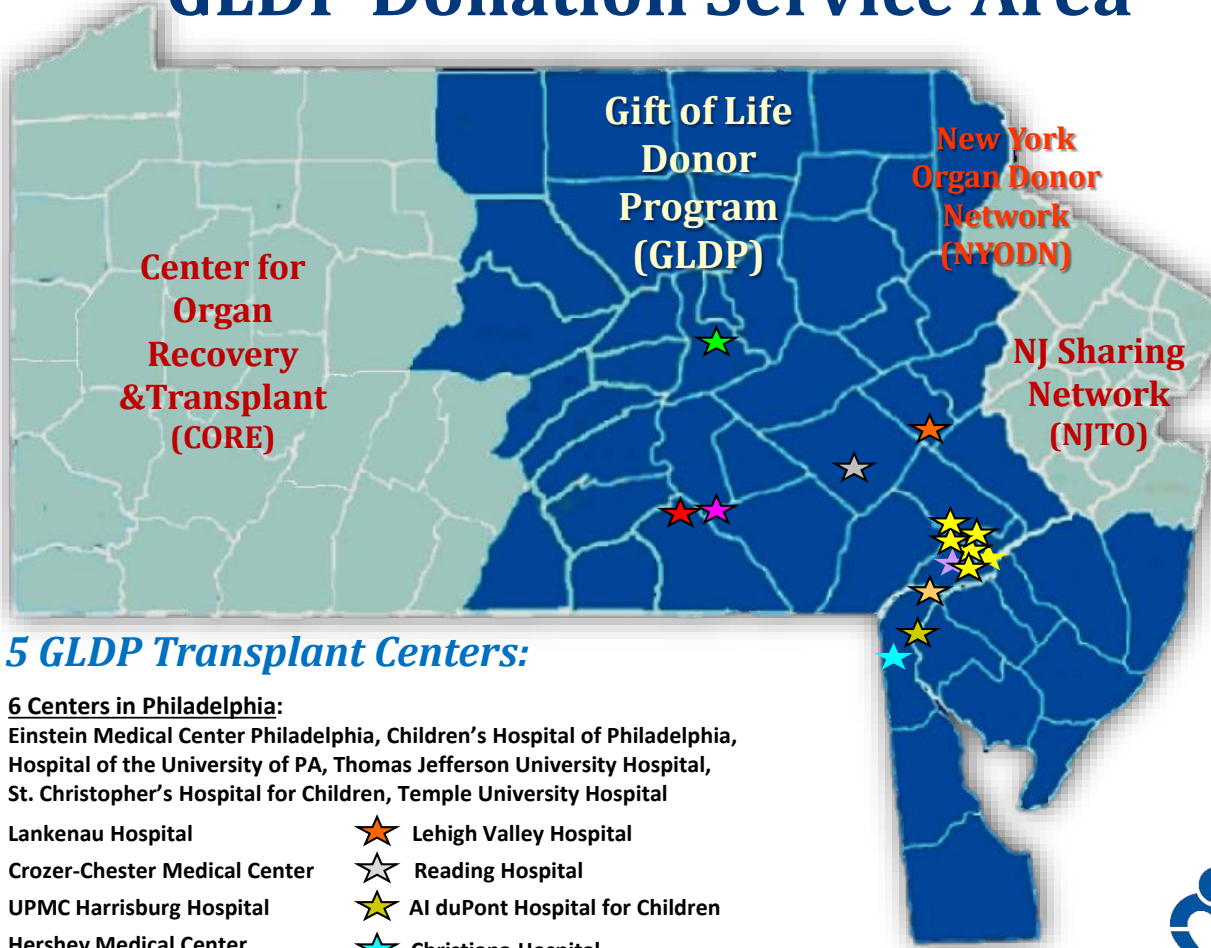
1974

5 Transplant Centers 5 to 15 Surgeons



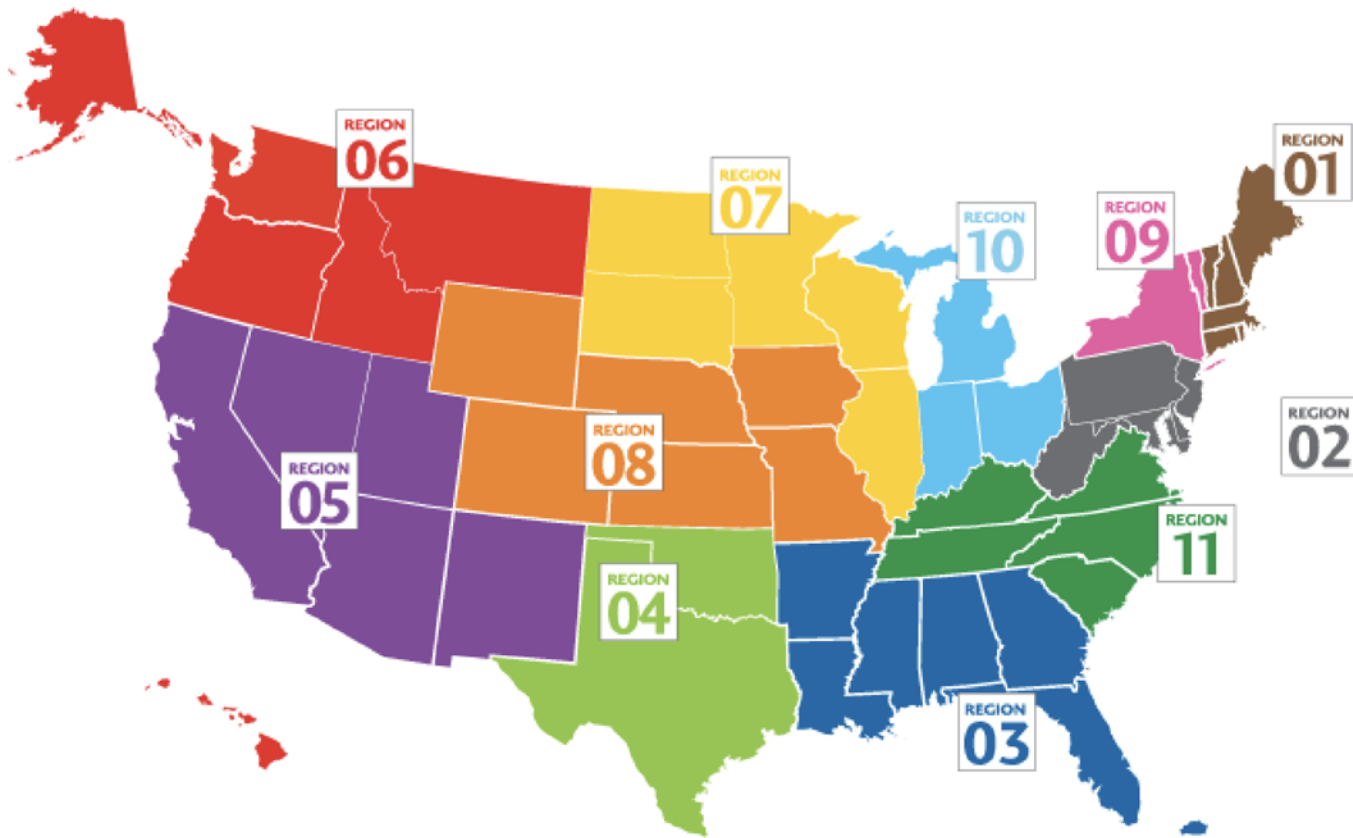
GIFT of LIFE
DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK
800-DONORS-1 • www.donors1.org

GLDP Donation Service Area



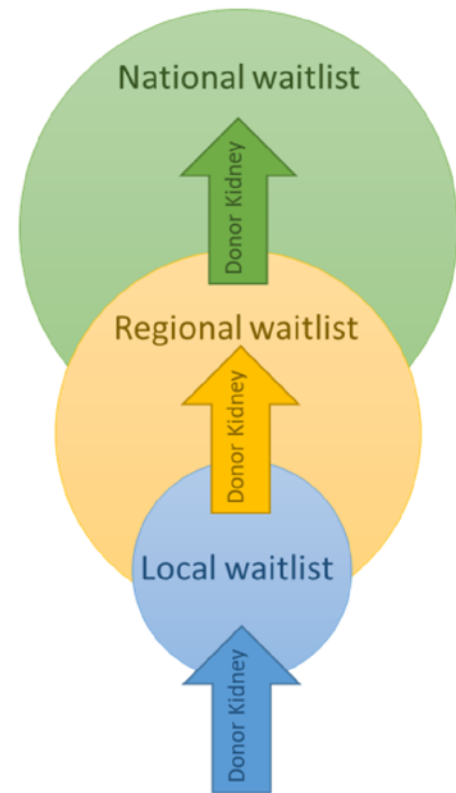
15 GLDP Transplant Centers:

- ★ **6 Centers in Philadelphia:**
Einstein Medical Center Philadelphia, Children's Hospital of Philadelphia, Hospital of the University of PA, Thomas Jefferson University Hospital, St. Christopher's Hospital for Children, Temple University Hospital
- ★ Lankenau Hospital
- ★ Crozer-Chester Medical Center
- ★ UPMC Harrisburg Hospital
- ★ Hershey Medical Center
- ★ Geisinger Medical Center
- ★ Lehigh Valley Hospital
- ★ Reading Hospital
- ★ AI duPont Hospital for Children
- ★ Christiana Hospital



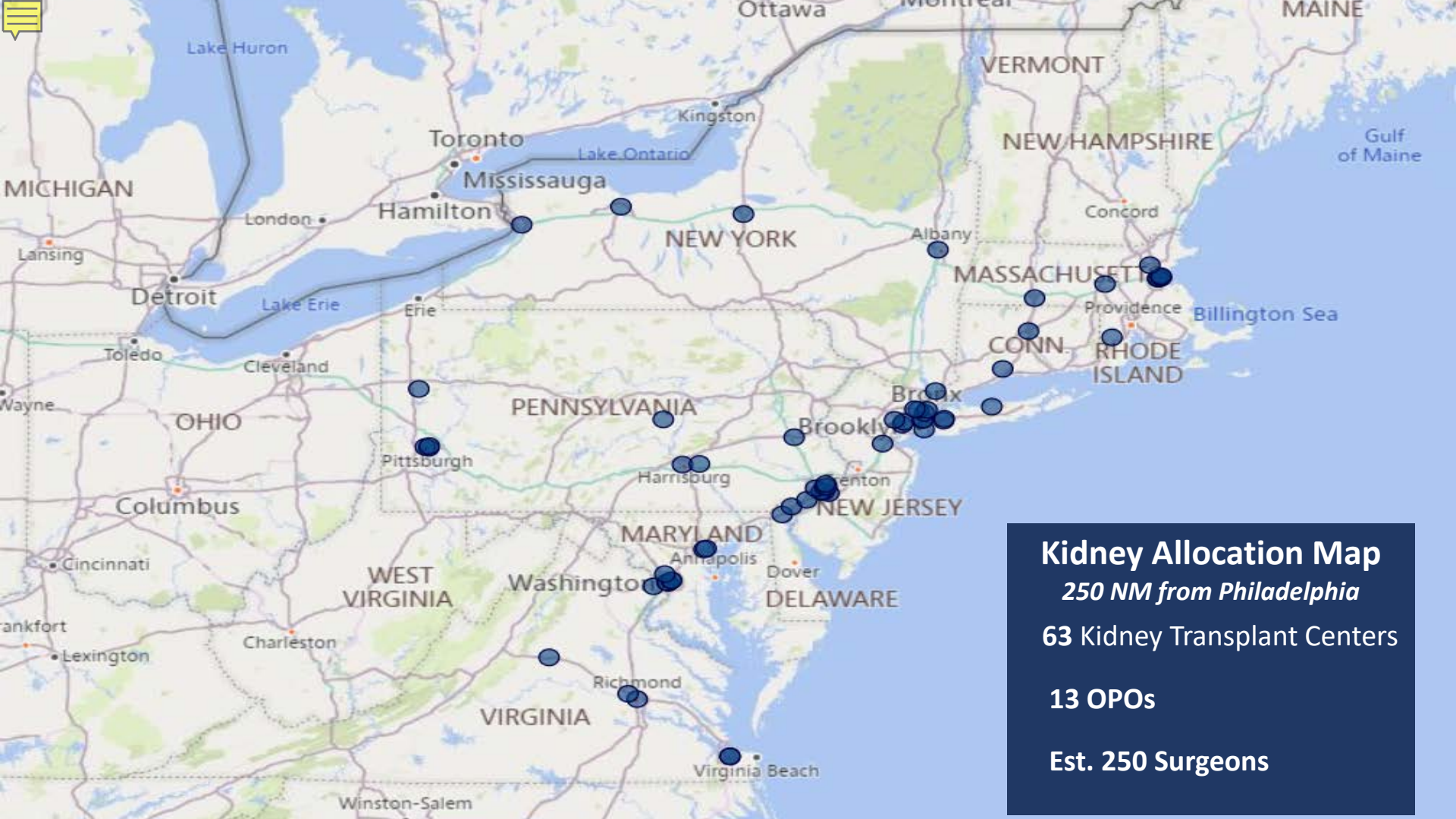
(a)

Geographic regions in the US



(b)

Geographical hierarchy of kidney offer process.



Kidney Allocation Map

250 NM from Philadelphia

63 Kidney Transplant Centers

13 OPOs

Est. 250 Surgeons

How OPOs are Financed in the United States

Direct Costs

- Donor Hospital
- Transportation (Air & Ground)
- Consultants
- Surgical Recovery
- Tissue Typing
- Infectious Disease Testing



Other Costs

- Salary & Benefits
- Employee Training
- Liability Insurance
- Medical Supplies
- Overhead / Building Operating Costs
- Call Center

Indirect Costs

Total Costs = Annual Budget

Divided by Number of Organs Transplanted

**= Organ Acquisition Charge (OAC)
Average fee per organ transplanted**

Bills Sent *Only* for Transplanted Organs

Transplant Centers

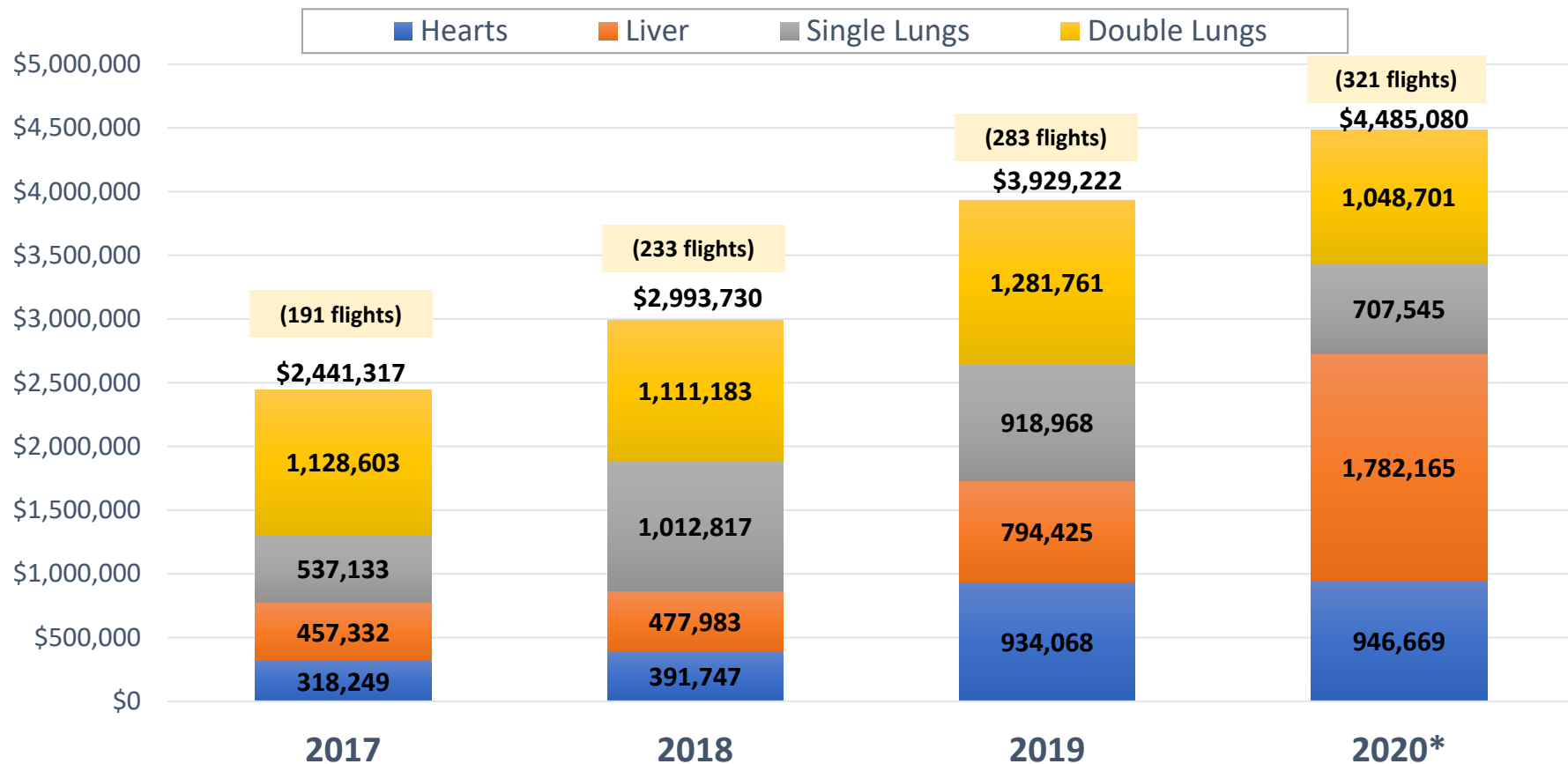
**OAC PAYMENT TO
THE OPO**

**Insurance Companies Pay
the Cost of the OAC and
Transplant Costs**

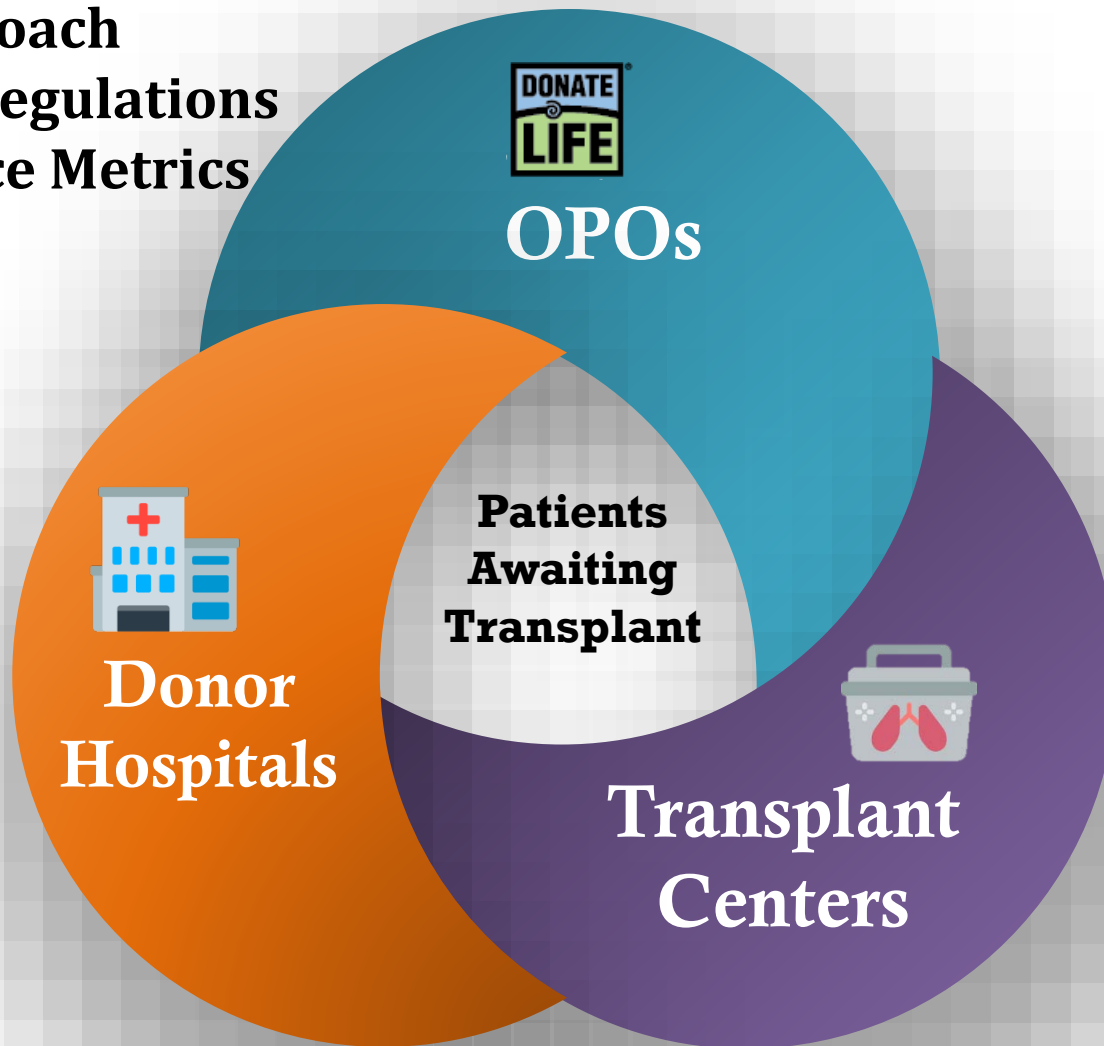
**OPO Establishes
"Costs Center"
for each organ type**

Gift of Life Imported Organ Transportation Costs *(by Organ)*

2017 – 2020



 **Systems Approach
for Aligning Regulations
& Performance Metrics**



FAIRNESS



UTILITY



EFFICIENCY



COSTS



COMPLEXITY



THANK YOU!



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