

Fourth Biennial
Transplant Donation Global Leadership Symposium 2016
May 22 – May 26, 2016 | L'Auberge Del Mar, California USA

United States Donation After Circulatory Death (DCD) Experience

Presented by:

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President & CEO



A Donate Life Organization

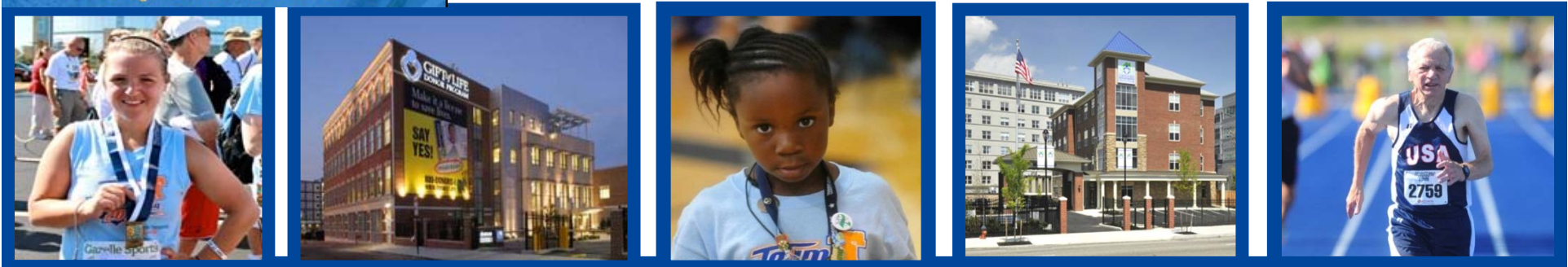


Transplant Donation
Global Leadership Symposium

A Hands-on Symposium for Advanced and Emerging Organ and Tissue Donation Leaders Worldwide



Fourth Biennial
**Transplant Donation
Global Leadership
Symposium 2016**
May 22 - 26, 2016
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OUR **TODAY**, THEIR **TOMORROW**:

Rewriting
the
stories...

What I Will Discuss Today

Background on DCDs in the United States

- Historical Perspective & Overview
- Statistics, Data and Analysis
- Regional Variations in Recovery and Transplantation of DCDs

Gift of Life Donor Program Philadelphia DCD Experience

- Implementation into OPO & Hospital Practice
- Clinical Practice
- Data

Future of DCD Practices. Estimation of DCD Pool and Extraordinary DCD Cases

Types of Donors

Brain Dead

- Death declared based upon neuro criteria
- Heart beat is intact

DCD

- Donation After Cardiac (Circulatory) Death
- Non-heart beating donation

Living

- Related or unrelated
- Directed or non-directed

Donation After Cardiac Death (DCD)

Definition:

A procedure whereby organs are surgically recovered following pronouncement of death based on “irreversible cessation of circulatory and respiratory functions.”

Controlled

Death & organ recovery can be predictably controlled following the withdrawal of life support.

Uncontrolled

Cardiac arrest is unplanned. Timing of other aspects of organ recovery are not controlled.

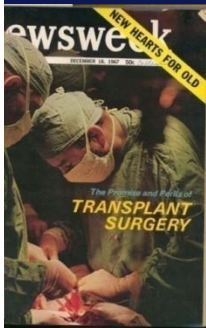
The Maastricht Categories of DCD Donors

<u>Category</u>	<u>Description</u>
I.	Dead on arrival (<i>Uncontrolled</i>)
II.	Unsuccessful resuscitation (<i>Uncontrolled</i>)
III.	Awaiting cardiac arrest (<i>Controlled</i>)
IV.	Cardiac arrest while brain dead (<i>Uncontrolled</i>)
V.	Cardiac arrest in a hospital inpatient (<i>Uncontrolled</i>)

Transplantation & DCD – Historical Perspective



1951- Hume, Kidney transplant



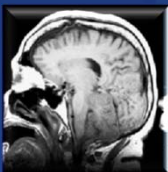
1963 - Starzl, Liver transplant



1967 - Barnard, Heart transplant



1968 – Harvard Committee
(Brain Death Criteria Established)

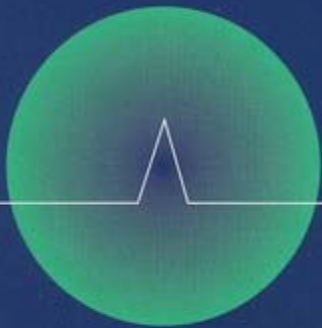


1970's – Acceptance of Brain Death Criteria

1990's – Re-evaluation of DCD



Non-Heart-Beating Organ Transplantation



Practice and Protocols

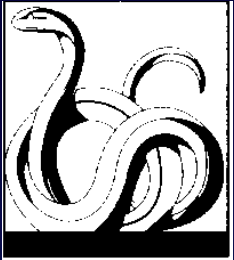
INSTITUTE OF MEDICINE

IOM Recommendation: Non-Heartbeating Donor Organ Donation (Donation after Cardiac Death)

“All organ procurement organizations (OPOs) should explore the option of non-heartbeating organ transplantation, in cooperation with local hospitals, health care professionals and communities.”

Source: IOM Study 2000





Institute of Medicine Recommendations

Policies and Oversight

Medical Interventions and Ethics

Conflicts of Interest

Determination of Death

Families

“In 1997, 2000, and 2005, the Institute of Medicine reviewed and voiced support for donation after cardiac death.”

“In 2005, a conference on donation after cardiac death concluded that it is “an ethically acceptable practice of end-of-life care, capable of increasing the number of deceased donor organs available for transplantation.” Bernat et al. AJT 2006; 6(2):281-291

Organ Donation after Cardiac Death

Robert Steinbrook, M.D.

Although the numbers of organ donors and transplantations in the United States have more than doubled over the past 20 years (see line graph), the demand for organs continues to dwarf

the supply. In 2006, there were about 29,000 solid-organ transplantations; as of June 2007, there were about 97,000 people on waiting lists for organ transplantation.

About three of every four organs that are transplanted are recovered from deceased donors. The most rapid increase in the rate of organ recovery from deceased persons has occurred in the category of donation after “cardiac death” — that is, a death declared on the basis of cardiopulmonary criteria (irreversible cessation of circulatory and respiratory functions) rather than the neurologic criteria used to declare “brain death” (irrevers-

ible loss of all functions of the entire brain, including the brain stem). Organs were recovered from 646 donors after cardiac death in 2006, as compared with 189 in 2002; these donors accounted for 8% of all deceased donors in 2006 (see bar graph). At the Organ Procurement Organization at the University of Wisconsin, the New England Organ Bank in the Boston area, and the Finger Lakes Donor Recovery Network in New York, such donors accounted for more than 20% of all deceased donors.

Since 1968, when an ad hoc committee at Harvard Medical School proposed a brain-based definition of death that became

widely accepted, organ transplantation has been primarily from living donors who have been on the basis of neurologic criteria, when they and their hearts have stopped. The continued circulation of blood helps to prevent organ damage from deterioration. Obtaining organs after cardiac death is not the approach followed in the United States. Today, such deaths involve patients who are older than 60 years of age and have such conditions as coronary artery disease, such as those who are on dialysis, or intracranial hemorrhage. Such patients

“In January 2007, the Joint Commission implemented its first accreditation standard for donation after cardiac death.”

OPTN/UNOS, has developed rules for donation after cardiac death... “As of July 1, 2007, OPTN/UNOS has required all 257 transplant hospitals and 58 organ-procurement organizations in the United States to comply with its new rules.”

Incidence of Deceleration of Care

Recommendations for end-of-life care in the intensive care unit: The Ethics Committee of the Society of Critical Care Medicine

Robert D. Truog, MD; Alexandra F. M. Cist, MD; Sharon E. Brackett, RN, BSN; Jeffrey P. Burns, MD; Martha A. Q. Curley, RN, PhD, CCNS, FAAN; Marion Danis, MD; Michael A. DeVita, MD; Stanley H. Rosenbaum, MD; David M. Rothenberg, MD; Charles L. Sprung, MD; Sally A. Webb, MD; Ginger S. Wlody, RN, EdD, FCCM; William E. Hurford, MD

Key Words: palliative care;

These recommendations are intended to provide guidance and advice for clinicians who deliver end-of-life care in intensive care units (ICUs). The number of deaths that occur in the ICU after withdrawal of life support is increasing, with one recent survey finding that 90% of patients who die in ICUs after a decision to limit therapy, though there is significant variation in the frequency of withdrawal of life support both within countries (2) and across cultures (3), the general trend is increasing in scope (4). Nevertheless, the evidence indicates that patient and family remain dissatisfied with the care

“The number of deaths that occur in the ICU after the withdrawal of life support is increasing, with one recent survey finding that 90% of patients who die in ICU’s now do so after a decision to limit therapy.”

technical skills that must be enlisted to provide a useful paradigm for the integration of

Recommendations for nonheartbeating organ donation

A Position Paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine

It is feasible to procure and then successfully transplant organs from cadavers certified dead using either neurologic or cardiac criteria. Kidneys procured from asystolic (nonheartbeating) cadavers have an equivalent 1-yr graft survival as those procured from donors certified dead using neurologic criteria (1). Recent controversy has erupted regarding the use of so-called nonheartbeating cadavers (NHBC). Questions have been raised about whether the patients are in fact dead (2), whether the practice constitutes active euthanasia (3), whether there is prohibitive conflict of interest for professionals and institutions (4, 5), whether there is adequate social support of dying patients and their families (6-8), and whether unethical and illegal practice is preventable (9).

Nonheartbeating organ donation (NHBOD) was commonplace before neurologic criteria for death were introduced in the late 1960s and early 1970s. During the 1960s, success with transplanting organs from cadaver donors led to the gen-

eral acceptance of the dead donor rule, which states that it is unethical to cause death by procuring organs and unethical for organ procurement to precede death (except in special circumstances like donation of a single kidney or partial liver from one family member to another). Although the use of cadaver organs rose rapidly in the late 1960s and early 1970s, the practice of procuring organs from NHBC declined and all but disappeared largely because transplanting organs from brain-dead donors had better outcomes than transplanting organs from NHBC (10). Because of patient and family requests and need for new donor sources, the practice reemerged in 1993 following introduction of the Pittsburgh Protocol (11). The practice of procuring organs from NHBC is increasing (12). As many as 20% of donors are in this class in certain procurement regions (Brosnick B, Center for Organ Recovery and Education, personal communication, February 2000). This newly resurgent practice has occurred without national consensus on guidelines.

Hospital and organ procurement organization policies are therefore variable, and some centers may even procure without an approved policy (12).

There have been a number of recent publications on NHBOD that have attempted to resolve ethical issues and set standards of practice. The most influential of those, the Institute of Medicine (IOM) report on NHBOD, supported the practice in principle. The IOM was commissioned by the United States Department of Health and Human Services to study the practice and make recommendations. Among their guidelines, they include a recommendation that a 5-min observation period after the onset of circulatory arrest, apnea, and unresponsiveness be required for death certification. Although the recommendation seems reasonable, it does not appear to consider data that may bear on their conclusion. The report is also silent regarding NHBOD in pediatric patients, even though pediatric NHBOD is possible, and there is one literature report of two pediatric NHBOD (13). Finally, little has been written about the psychosocial support of patients who become nonheartbeating organ donors and their families.

The purpose of this article is to comment on the issues of timing of death, pediatric NHBOD, and support of patients and their families. Because the Society of Critical Care Medicine (SCCM) is a multidisciplinary group of critical care professionals with expertise and experience in resuscitation as well as the management of critically ill patients who are dying and refuse life support, it is uniquely positioned to address NHBOD. In addition, the psychosocial care of dying patients and their families is a major focus of those working in a critical care environment. Therefore, we will offer specific recommendations addressing this concern. This article will not define specific medical eligibility or exclusionary criteria for NHBOD, nor will it comment upon the other ethical and legal

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Key Words: nonheartbeating organ donation; organ transplantation; ethics; end-of-life care; pediatric organ donation; death determination.
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“It is the consensus opinion of the Ethics Committee of the Society of Critical Care Medicine that death determination for both intensive care unit patients and potential nonheartbeating donors should utilize the same criteria within a single institution.”

Society of Critical Care Medicine

Critical Care Medicine 2001 Vol. 29, No 9



General Recommendations

DCD is medically acceptable and ethical provided informed consent is obtained from patient or designee

Informed consent is ethical cornerstone - special training required for those obtaining consent due to complexity

Death must be certified using standardized, objective, and auditable criteria and must follow state law

It is ethically reasonable for DCD to occur with pediatric patients

If, in the process of delivering high quality end-of-life care, organ donation is possible then the professional should support that outcome



MEETING SUMMARY • DECEMBER 20, 2006

MOVING FORWARD IN INCREASING ORGAN DONATION: OPPORTUNITIES AND BARRIERS TO UNCONTROLLED DCDD IN MAJOR METROPOLITAN CITIES

On December 20, 2006, the Institute of Medicine (IOM) held a meeting focused on disseminating the recommendations of the IOM report, *Organ Donation: Opportunities for Action* with particular attention to the next steps regarding uncontrolled donation after circulatory determination of death (DCDD). The meeting addressed opportunities and barriers for building public and professional consensus and implementing uncontrolled DCDD programs in major metropolitan areas. Three cities (Chicago, New York City, and Washington, D.C.) served as examples for discussion. Participants in the meeting (listed at the end of this summary) included transplant surgeons, emergency response personnel, hospital administrators, emergency care professionals, organ procurement organization (OPO) staff, ethicists, and health policy and government representatives. In accordance with IOM policy on dissemination meetings, all statements in this summary are attributed to specific speakers, and the summary does not contain additional IOM recommendations.

Jim Childress and Jim DuBois co-chaired the meeting and, building on the IOM report, introduced uncontrolled DCDD as an opportunity to significantly increase the potential number of organs for transplantation and to provide an option for donation to greater numbers of individuals. Dr. DuBois asked the group to consider the issues relevant to the feasibility of uncontrolled DCDD and whether uncontrolled DCDD is actually feasible to organ donation after neurologic determination of death (DNDD or "brain death").

OVERVIEW OF THE ISSUES

Lewis Goldfrank opened his presentation with an overview of the issues by reminding the group that many people who die never have the opportunity to be organ donors.

In reviewing the common forms of donations, he noted that there are approximately 7,000 living donations of single organs each year. Neurological determination of death accounts for approximately 23,000 transplanted organs annually from just over 7,500 DNDD donors, although the potential exists for 12,000 to 16,000 DNDD donors. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations. Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

Dr. Goldfrank noted the need for clearer terms and definitions, for instance, in the categorization frameworks, such as the Masaricki categories. He stressed the difficulties in defining and distinguishing controlled versus uncontrolled dying. Donation after circulatory determination of death is termed "uncontrolled" when death is due to unexpected or sudden circulatory-respiratory arrest.

Presently, there are more than 94,000 individuals on the U.S. organ transplant waiting list.

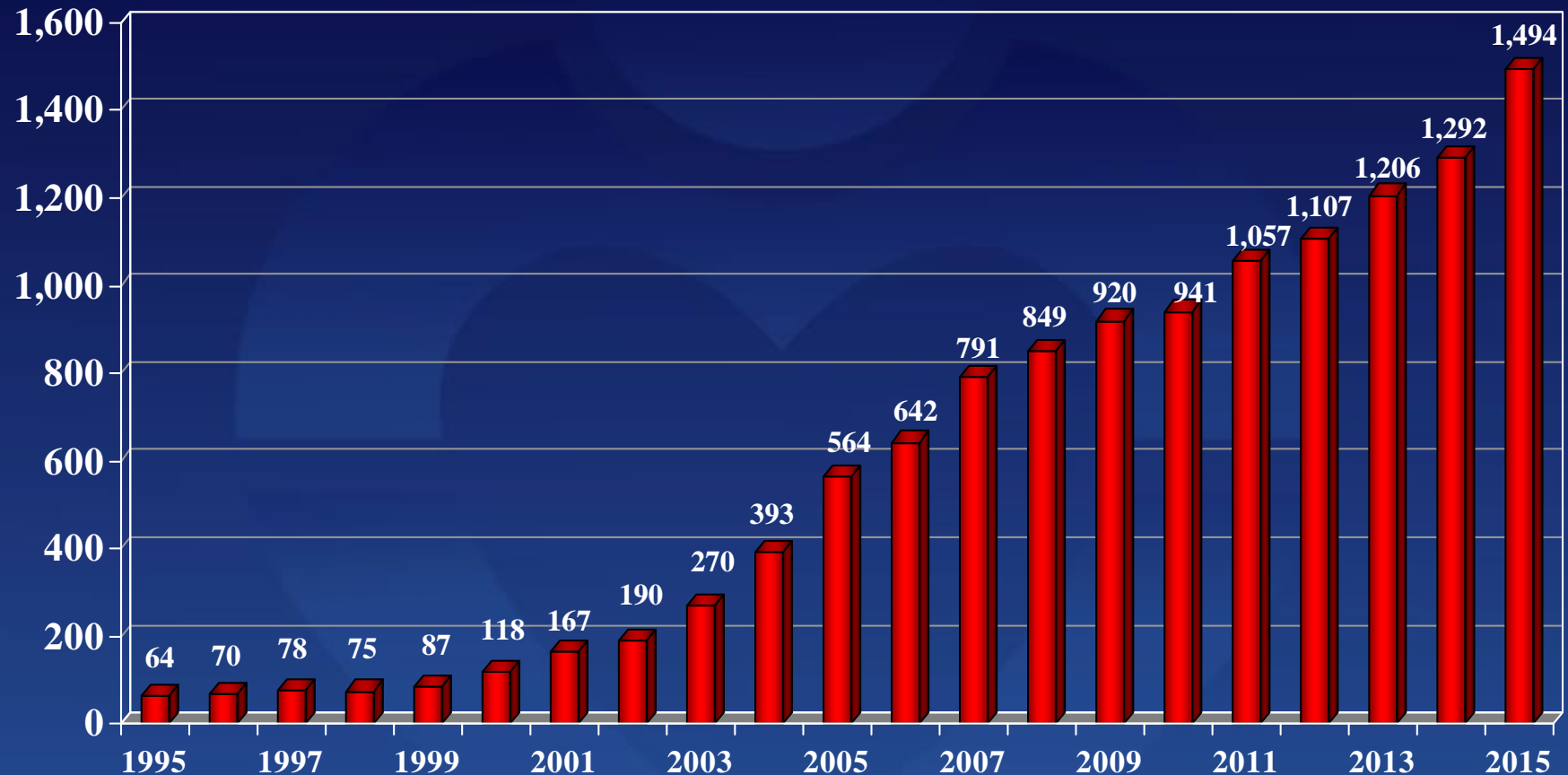
Donation after circulatory determination of death (DCDD) is termed "uncontrolled" when death is due to unexpected or sudden circulatory-respiratory arrest. Circulatory determination of death currently accounts for only 5.5 percent of deceased donations.

IOM report developed by a group of transplant professionals to address feasibility of uncontrolled Donation After Cardiac Death Determination (DCDD)

Findings promote the need for educational efforts in order to gain acceptance of uncontrolled DCDD

22,000 potential uncontrolled DCD donors estimated in U.S. annually—the largest number of unused organ donors

U.S. Growth In Donation after Cardiac Death 1995 – 2015



In 2015, DCD donors provided 2,876 life-saving organ transplants

Source: Based on OPTN data through December 31, 2015. Data subject to change due to future data submission or correction.

U.S. OPO Experience – Organ Donors / DCDs 1995 – 2015

Year Donor Recovered	Total Donors (includes DCDs)	Total DCDs	DCD Percent of Total	Number of OPOs with at least one DCD
1995	5,363	64	1.2%	22
1996	5,418	70	1.3%	21
1997	5,479	78	1.4%	19
1998	5,793	75	1.4%	16
1999	5,824	87	1.7%	18
2000	5,985	118	1.9%	22
2001	6,080	167	2.7%	29
2002	6,190	190	3.1%	31
2003	6,457	270	4.1%	32
2004	7,150	393	5.4%	43
2005	7,593	564	7.4%	49
2006	8,017	642	8.0%	54
2007	8,085	791	9.8%	57
2008	7,989	849	10.6%	55
2009	8,022	920	11.5%	55
2010	7,943	941	11.8%	55
2011	8,126	1,057	12.9%	57
2012	8,143	1,107	13.6%	56
2013	8,268	1,206	14.6%	57
2014	8,596	1,292	15.0%	57
2015	9,080	1,494	16.5%	57

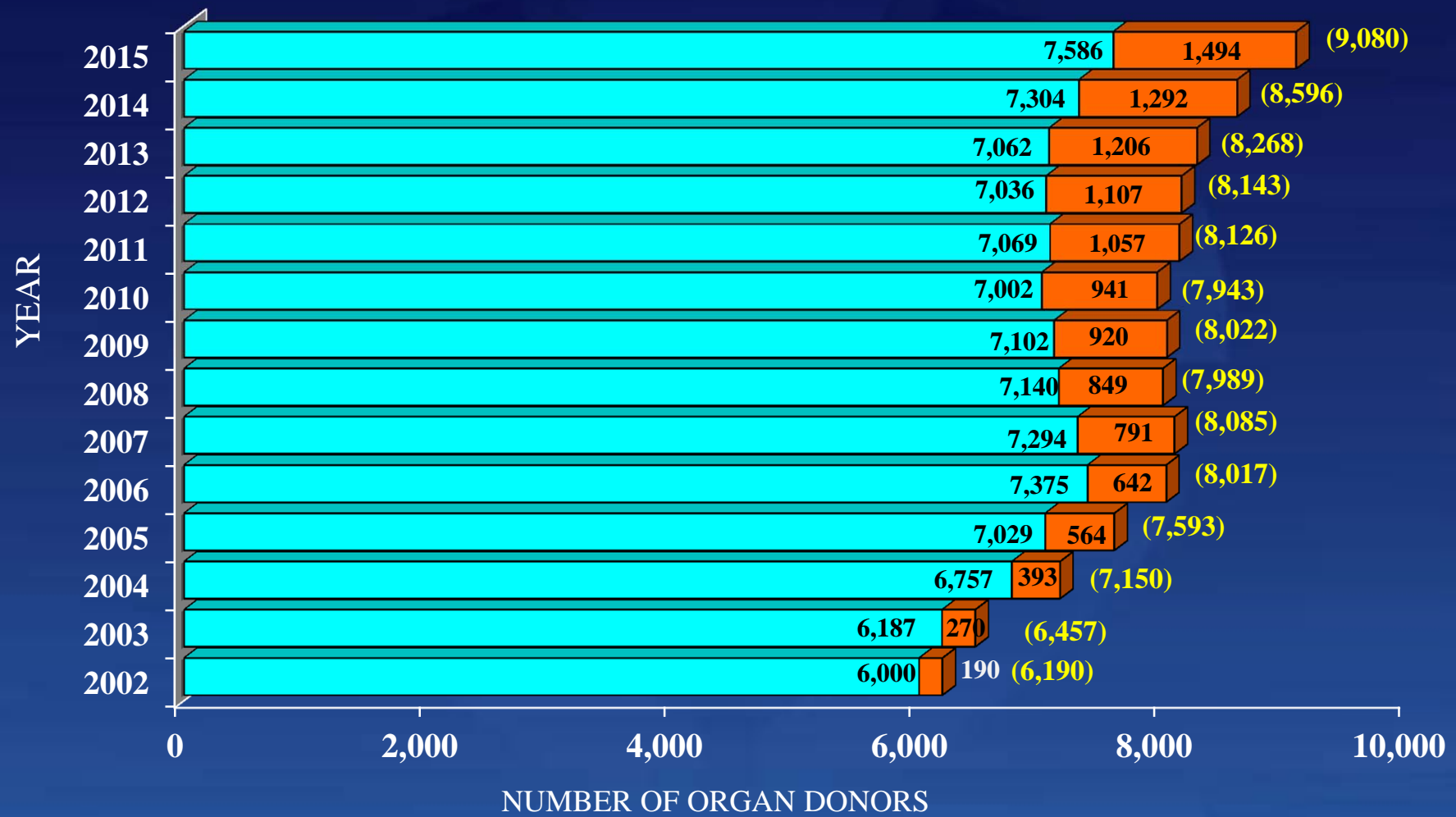
Source: Based on OPTN data through December 31, 2015.



U.S. Organ Donor Experience – DBD & DCD Donors 2002 – 2015

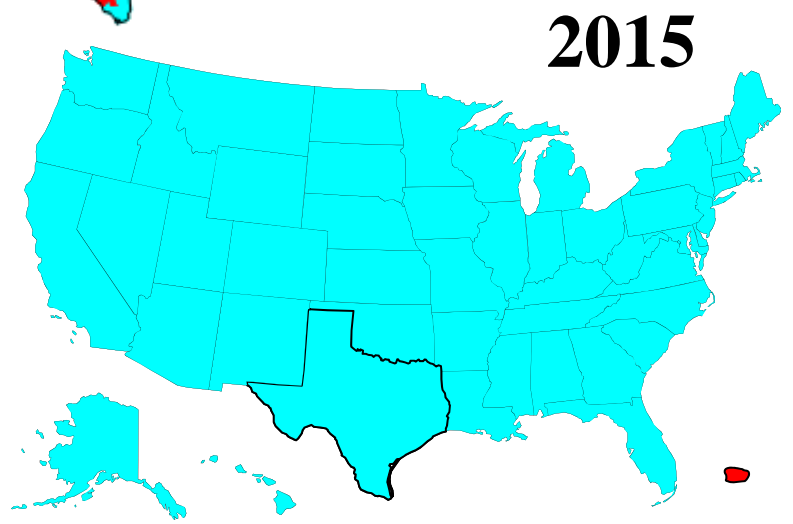
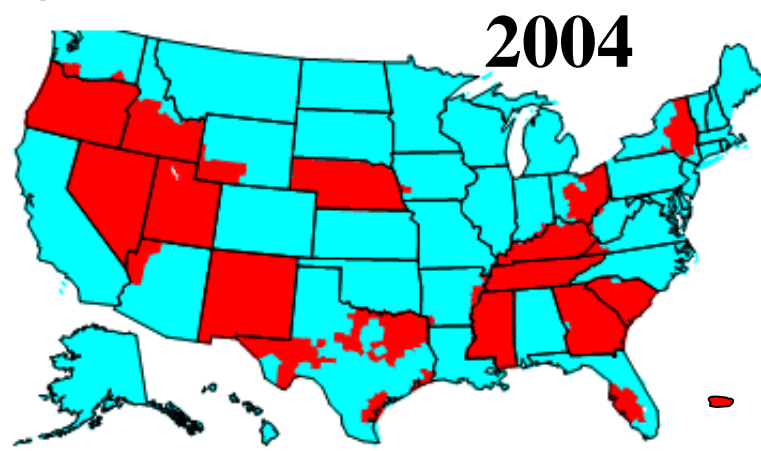
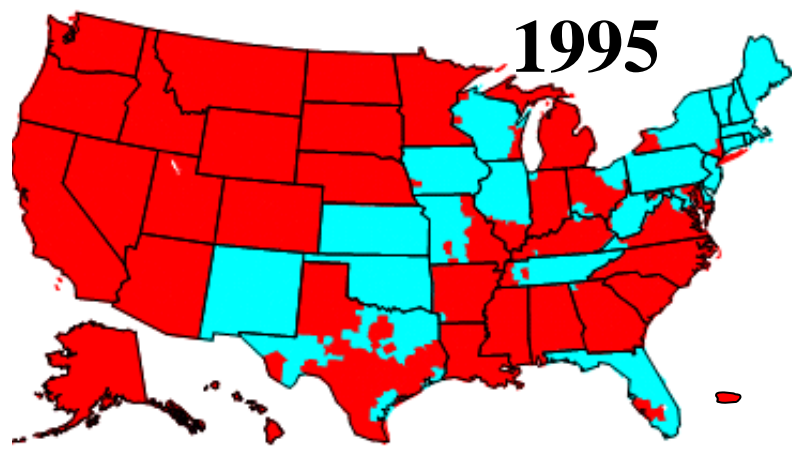
Total Deceased Organ Donors = 109,659

■ BD (n=97,943) ■ DCDs (n=11,716)



Source: Based on OPTN data through December 31, 2015.

DCD Recoveries by OPO



Number Recovered:
■ None Recovered
■ At Least 1 Recovered



National DCD Experience – Number of DCD Donors Recovered/Transplants
January 1, 2004 – December 31, 2015

	Number of DCD Donors	NUMBER OF ORGANS TRANSPLANTED						
		TOTAL	KIDNEY	LIVER	PANCREAS	LUNGS	HEART	INTESTINE
<u>Year</u>								
2004	393	790	566	184	29	10	1	0
2005	564	1,112	795	272	32	13	0	0
2006	642	1,362	1,014	289	35	24	0	0
2007	791	1,521	1,171	306	25	16	3	0
2008	849	1,651	1,308	277	32	34	0	0
2009	920	1,769	1,385	289	39	56	0	0
2010	941	1,798	1,468	269	36	24	1	0
2011	1,057	2,103	1,766	270	33	34	0	0
2012	1,107	2,010	1,699	263	16	32	0	0
2013	1,206	2,273	1,889	309	19	56	0	0
2014	1,292	2,551	2,087	364	26	74	0	0
2015	1,494	2,876	2,332	405	25	114	0	0
Total	11,256	21,816	17,480	3,497	347	487	5	0

Source: Based on OPTN data through December 31, 2015. Data subject to change due to future data submission or correction.

14 OPOs Recovering > 35 DCDs: 2015

OPO	Deceased Donors	DCD Donors	% DCD
New England Organ Bank (CT, MA, ME, NH, RI, VT)	282	85	30%
Gift of Life Donor Program (DE, NJ, PA)	483	83	17%
Gift of Life Michigan (MI)	285	74	26%
Gift of Hope Organ & Tissue Donor Network (IL & IN)	379	73	19%
OneLegacy (CA)	460	60	13%
LifeCenter Northwest (AK, ID, MT, WA)	200	50	25%
Midwest Transplant Network (KS & MO)	200	47	24%
LifeGift Organ Donation Center (TX)	283	46	16%
LifeShare Transplant Donor Services of Oklahoma (OK)	174	42	24%
Donor Network of Arizona (AZ)	166	39	23%
LifeSource Upper Midwest (MN, ND, SD & WI)	154	39	25%
Carolina Donor Services (NC & VA)	159	36	23%
Pacific Northwest Transplant Bank (OR, ID & WA)	120	36	30%
Center for Organ Recovery and Education (NY, PA & WV)	207	36	17%

14 of 58 OPOs (24%) recovered 746 of the 1,494 DCDs (50%)



National DCD Donors

January 1, 2015– December 31, 2015

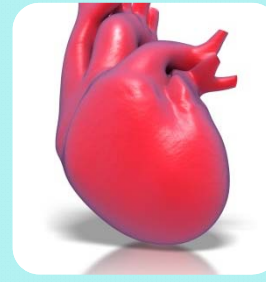
	Total Donors*	DCD Donors	DCD % of Total	DCD Organs Transplanted	Organs Transplanted Per Donor
All Organ Procurement Organizations	9,080	1,494	16%	2,876	1.93

Source: Based on OPTN data through December 31, 2015. Data subject to change due to future data submission or correction.

** Total Donors based upon deceased donors only.*

Life-Saving Organ Transplants from U.S. DCD Donors *January, 2015 – December, 2015*

(Total DCD Donors = 1,494)



2,332

Kidneys

405

Livers

25

Pancreas

114

Lungs

0

Hearts

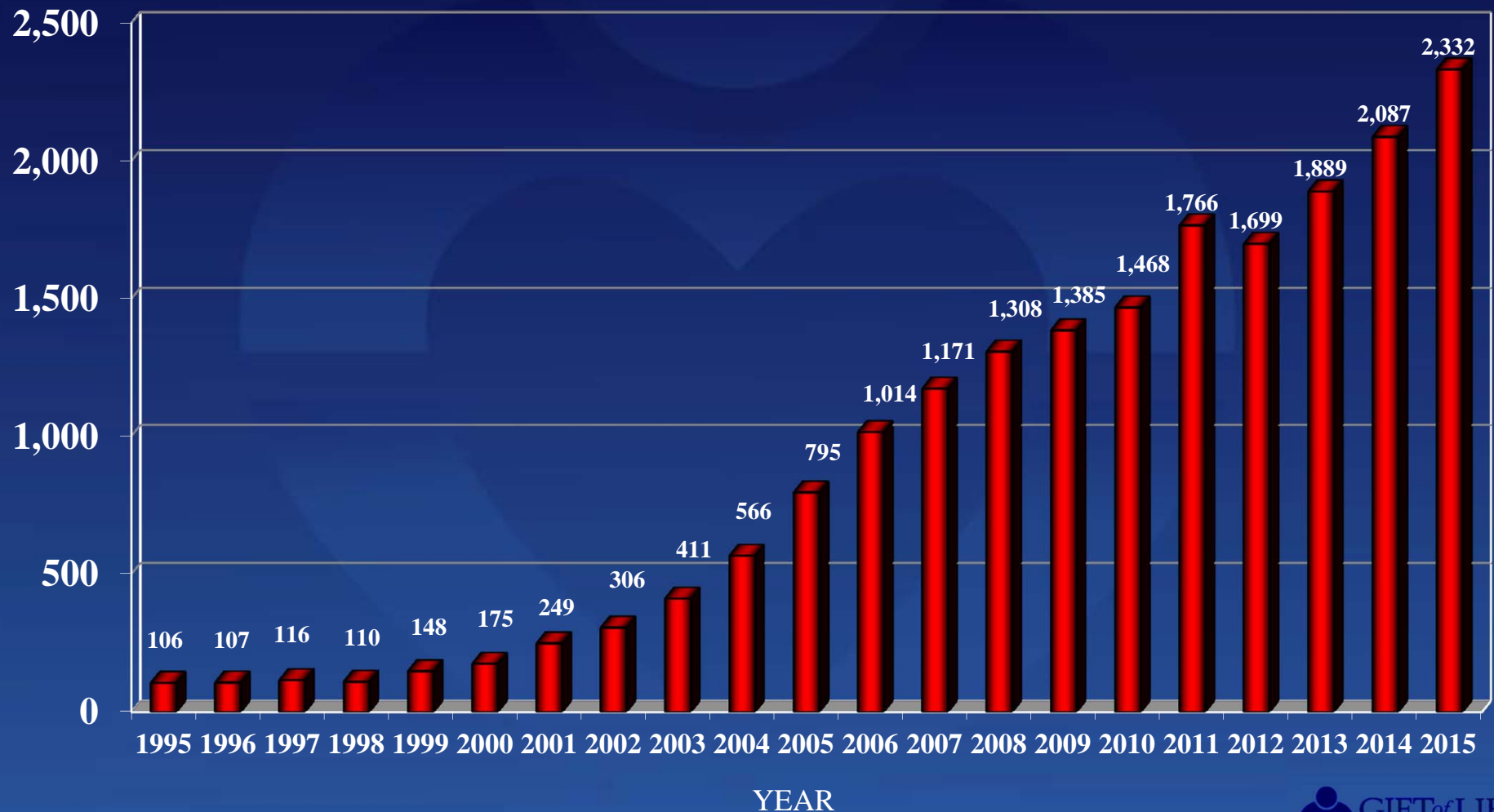
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Intestine

Source: Based on OPTN data through December 31, 2015 . Data subject to change due to future data submission or correction.

DCD Kidney Transplants in the United States 1995 – 2015

(n=19,208)



Source: Based on OPTN data through December 31, 2015.

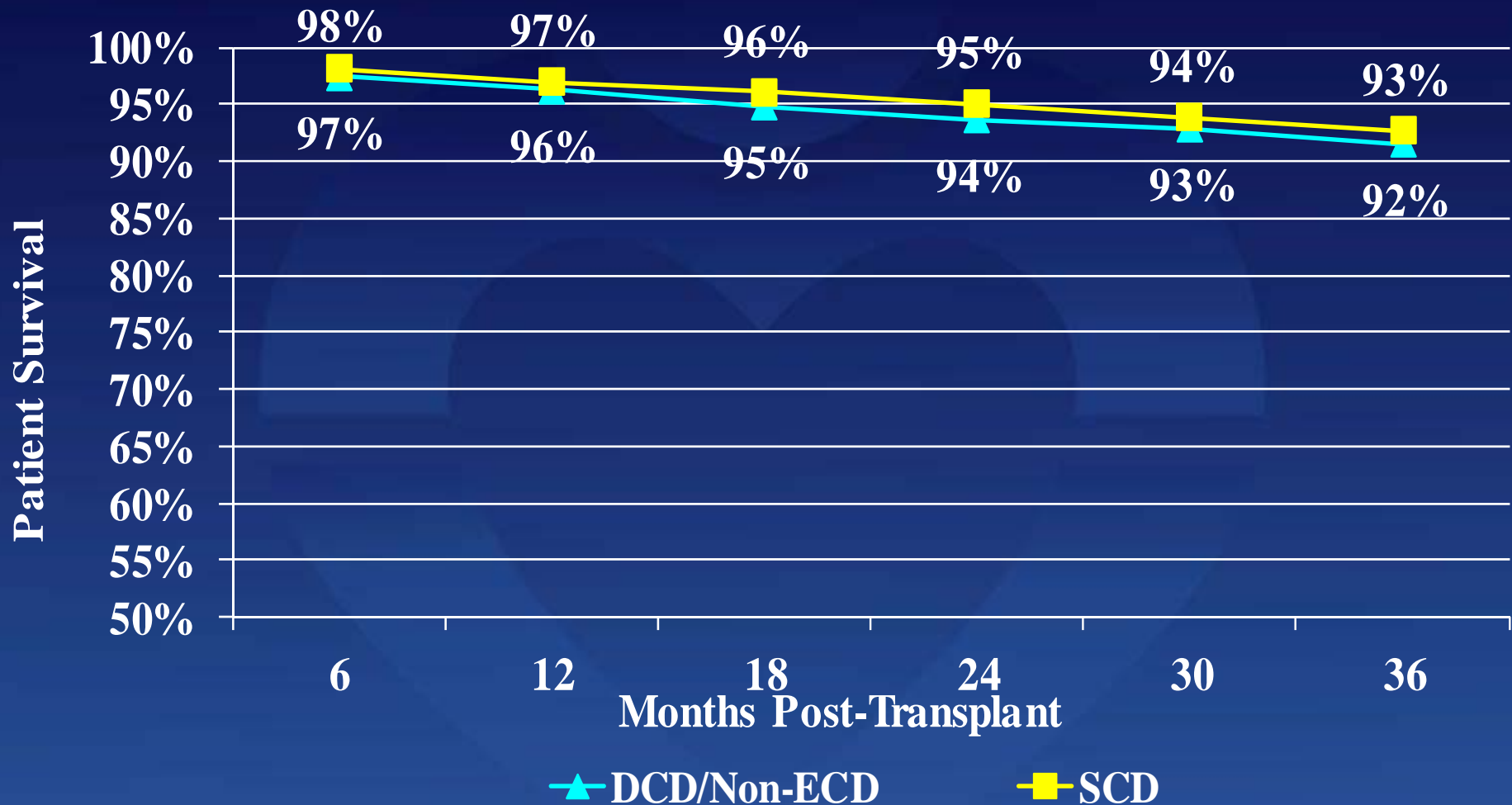


DCD Kidney Utilization in the U.S. 2008 – 2015



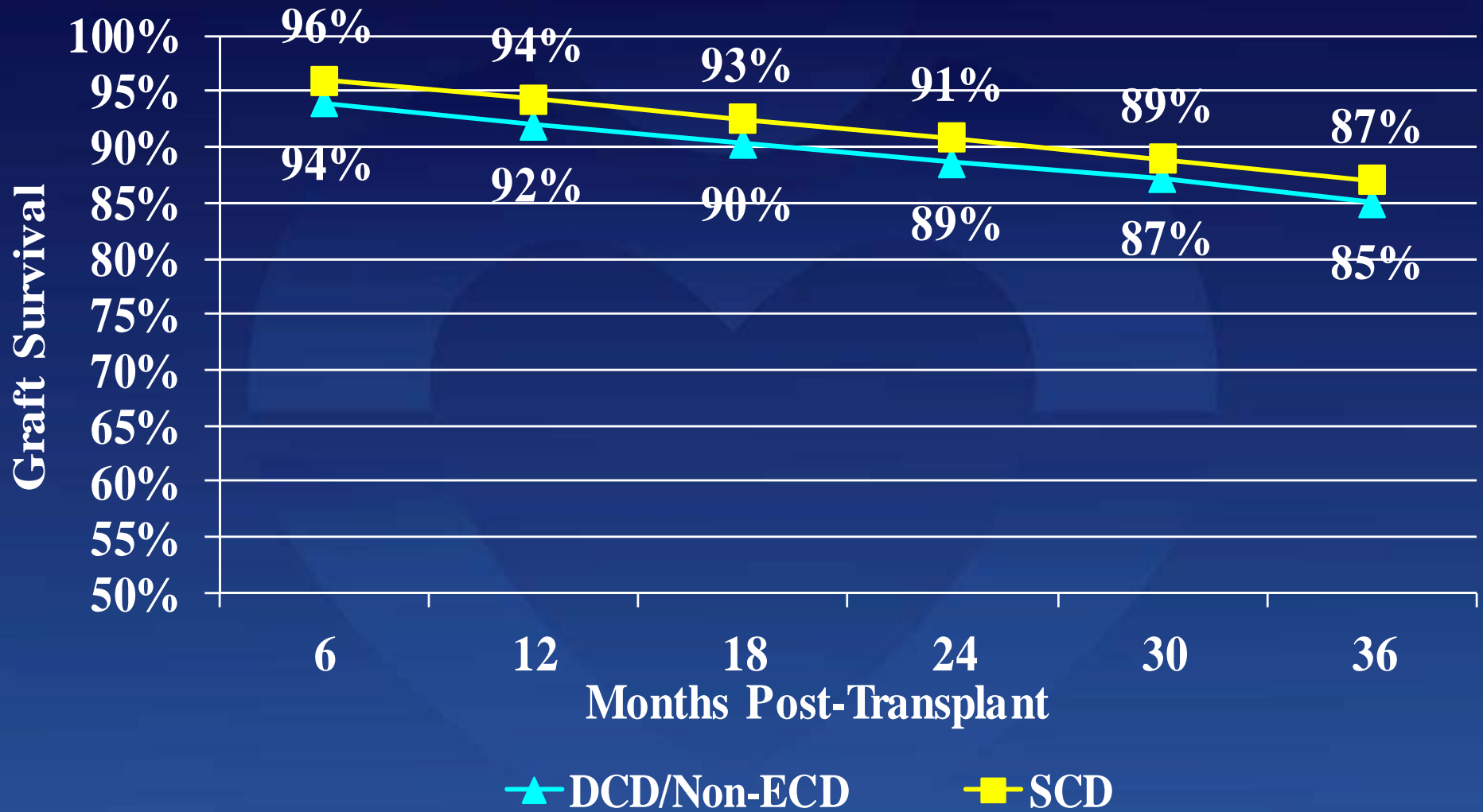
Source: Based on OPTN data through December 31, 2015.

3-Year U.S. Kaplan Meier Kidney Patient Survival DCD/Non-ECD vs. SCD 1/1/2010 – 12/31/2012



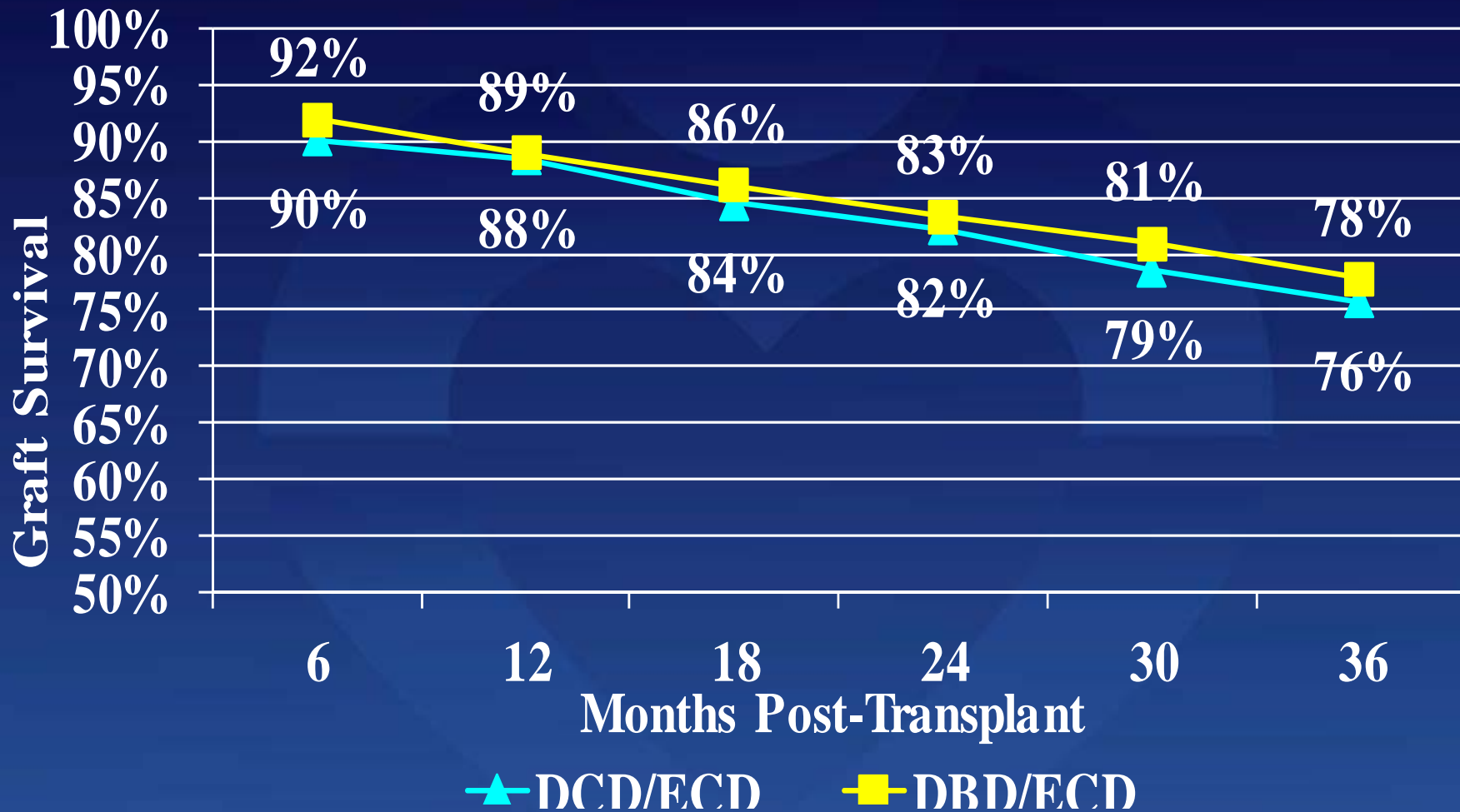
Source: Based on OPTN Data as of March 11, 2016

3-Year U.S. Kaplan Meier Kidney Graft Survival DCD/Non-ECD vs. SCD 1/1/2010 – 12/31/2012



Source: Based on OPTN Data as of March 11, 2016

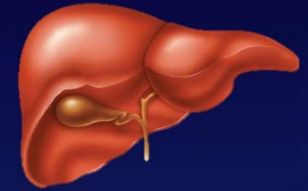
3-Year U.S. Kaplan Meier Kidney Graft Survival DCD/ECD vs. DBD/ECD 1/1/2010 – 12/31/2012



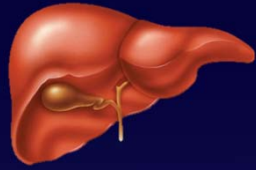
Source: Based on OPTN Data as of March 11, 2016

DCD Liver Transplants in the United States 1995 – 2015

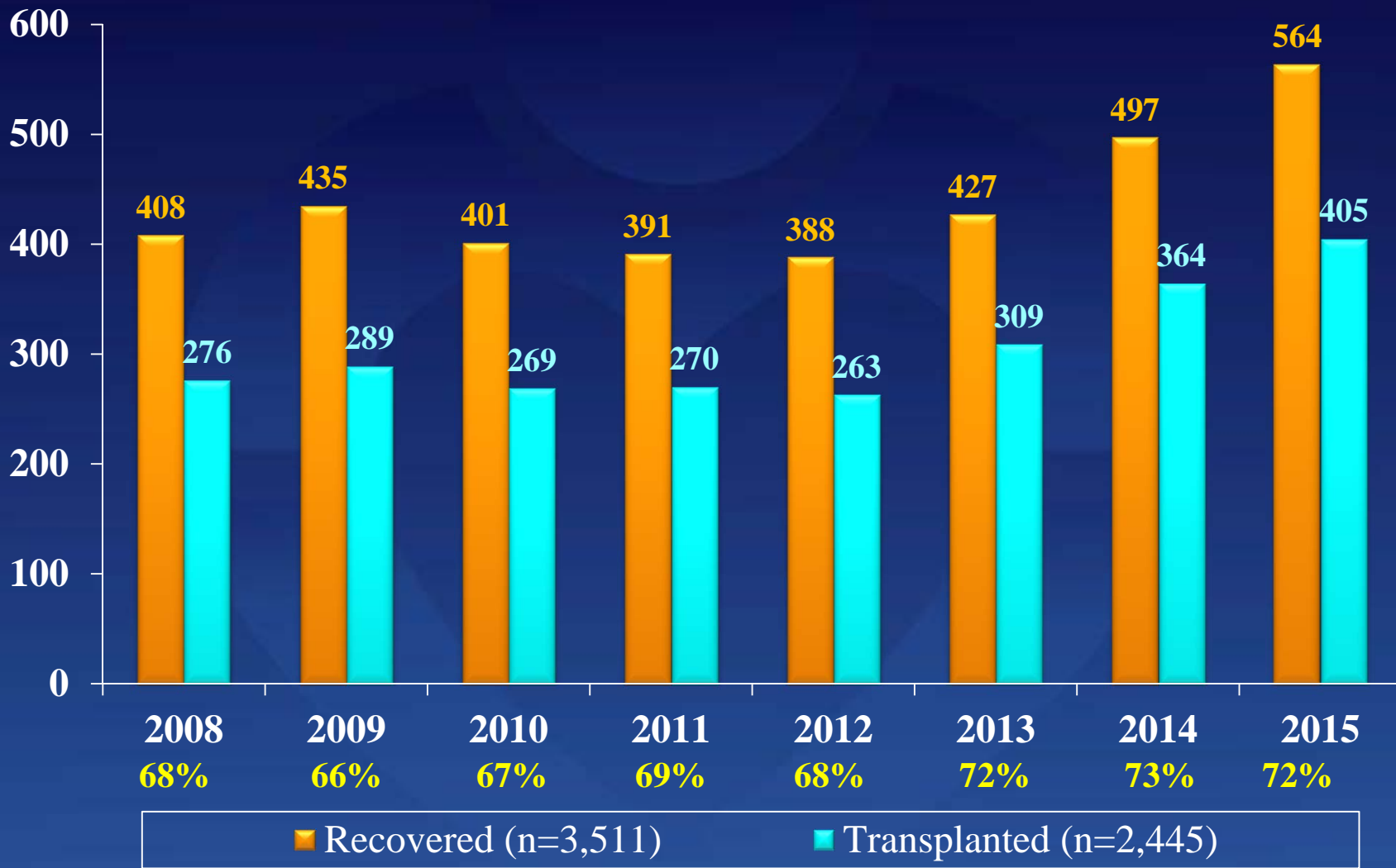
(n=3,878)



Source: Based on OPTN data through December 31, 2015.

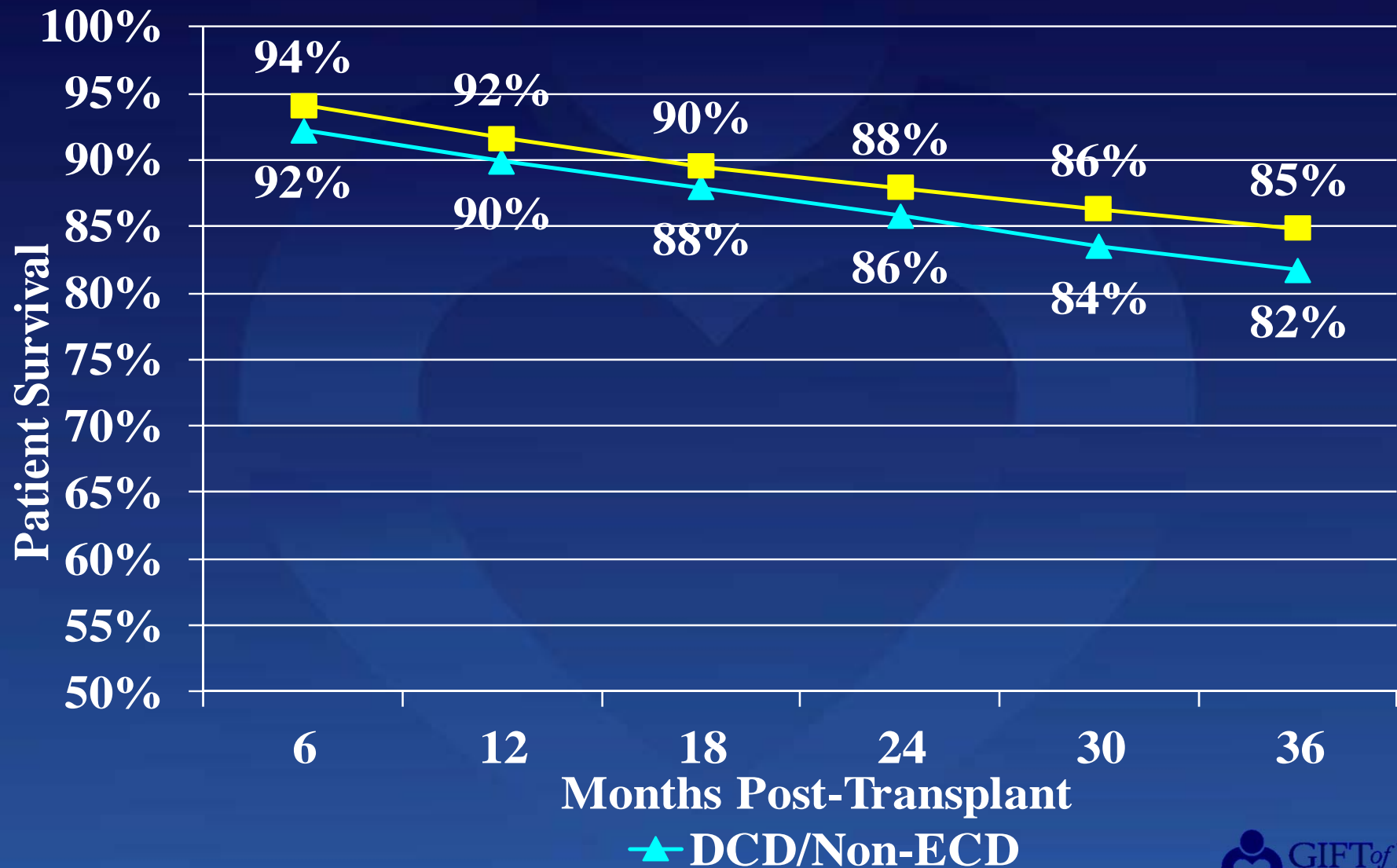


DCD Liver Utilization in the U.S. 2008 – 2015



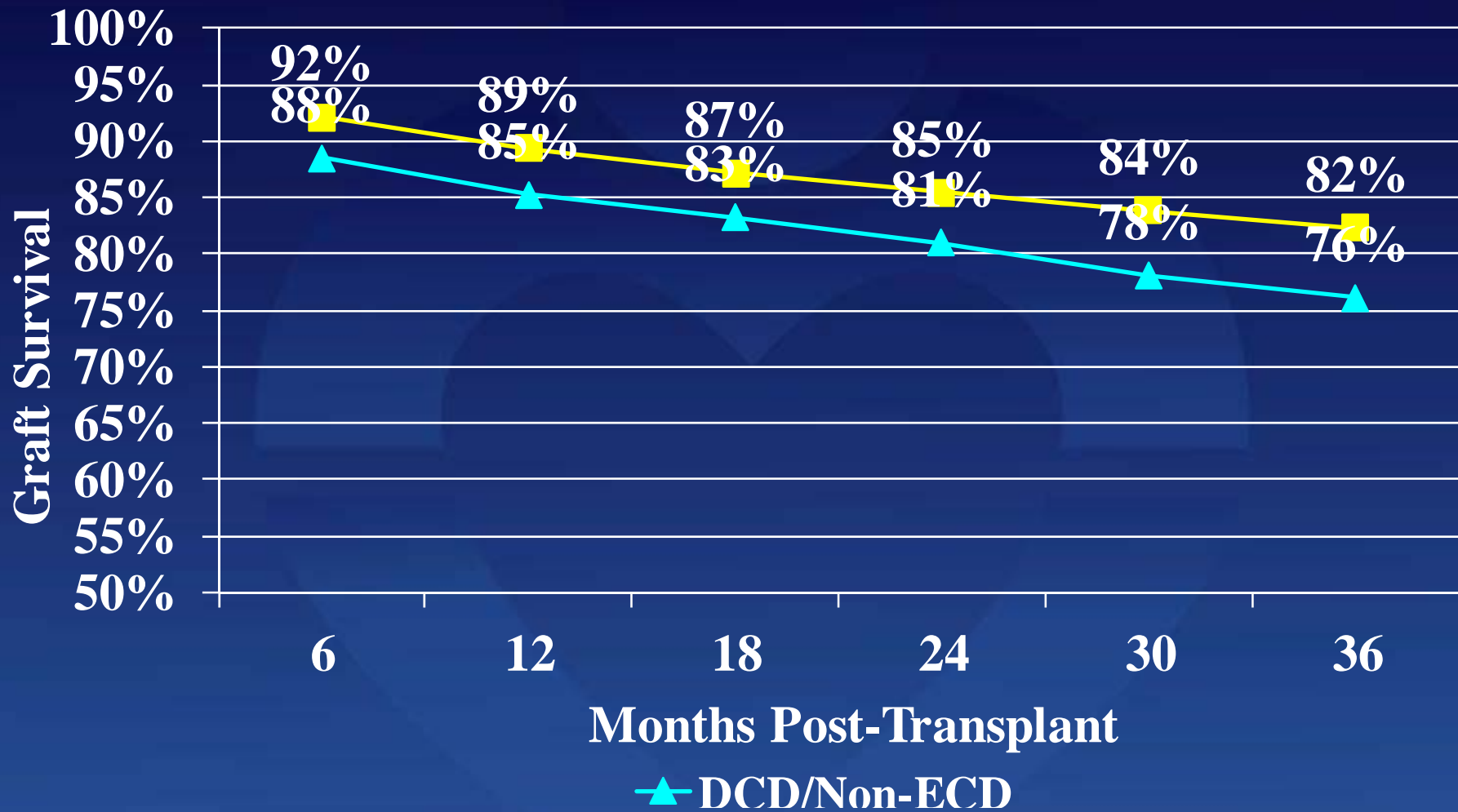
Source: Based on OPTN data through December 31, 2015.

3 Year U.S. Kaplan Meier Liver Patient Survival DCD/Non-ECD vs. SCD 1/1/2010 – 12/31/2012



Source: Based on OPTN Data as of March 11, 2016

3 Year U.S. Kaplan Meier Liver Graft Survival DCD/Non-ECD vs. SCD 1/1/2010 – 12/31/2012



Source: Based on OPTN Data as of March 11, 2016





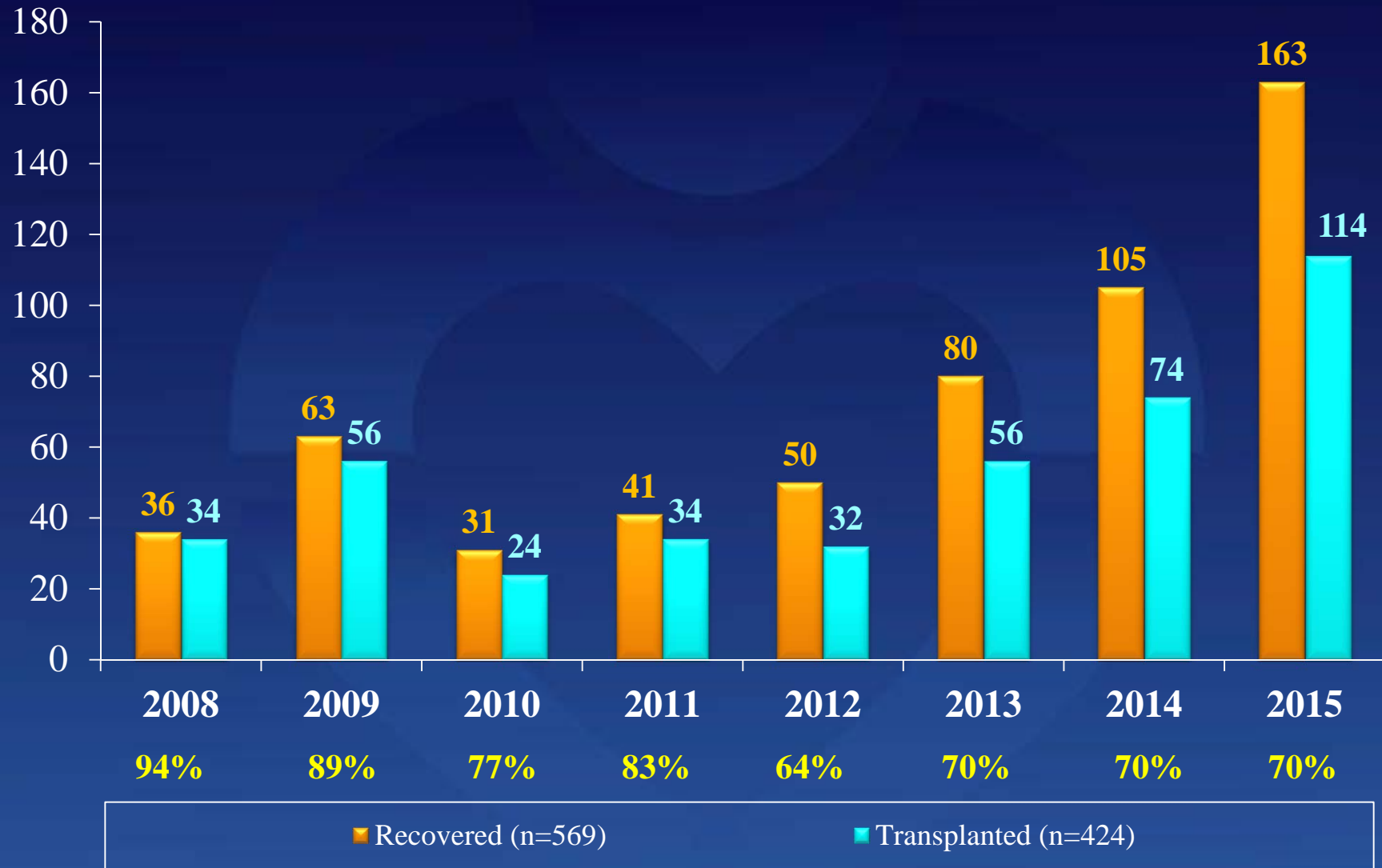
DCD Lung Transplants in the United States 2004 – 2015

(n=477)



Source: Based on OPTN data through December 31, 2015.

DCD Lung Utilization in the U.S. 2008 - 2015



Source: Based on OPTN data through December 31, 2015.

Gift of Life Donor Program

Philadelphia, Pennsylvania USA



- Non-Profit OPO/Tissue Recovery/Eye Bank
- Established in 1974
- Largest OPO in the United States
- Federally designated OPO (by Medicare) for eastern PA, Southern NJ & Delaware
 - 129 Acute Care Hospitals
 - 15 Transplant Centers, 42 Programs
 - 11 Million Population

- **483 organ donors in 2015, resulting in 1,291 transplants;** highest volume in the U.S. – 44 donors/MM; 1,202 bone recoveries; 2,265 cornea recoveries and 2,546 tissue recoveries

- Over 40,000 organs for transplantation and over 550,000 tissue allografts
- Accredited by: Association of Organ Procurement Organizations (AOPO); American Assoc. of Tissue Banks (AATB) & Eye Bank Assoc. of America (EBAA); UNOS/OPTN member OPO



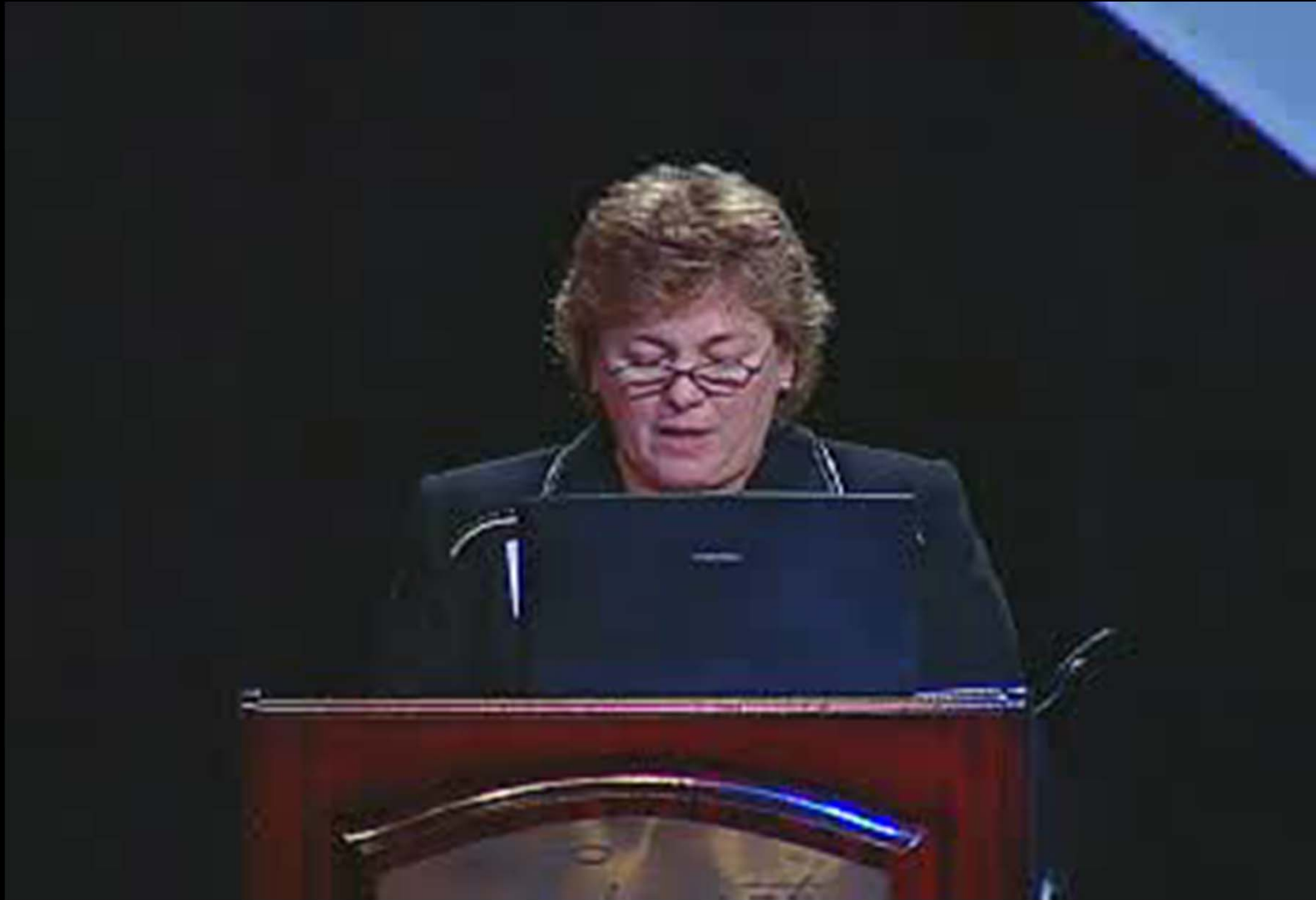
A Mother's Perseverance Changed Gift of Life's Practice

• *“For my family, donation wasn't about the process, it was about the outcome.”*

~ Susan McVey-Dillon
Donor Mother
June, 1995

Like all end-of-life care, the DCD process is committed to the care of the patient and meeting the needs of the family.





*Sue McVey Dillon,
Mother of Gift of Life's First DCD Donor
Speaking at the U.S. National Learning Congress in 2005*

Gift of Life Donor Program Results

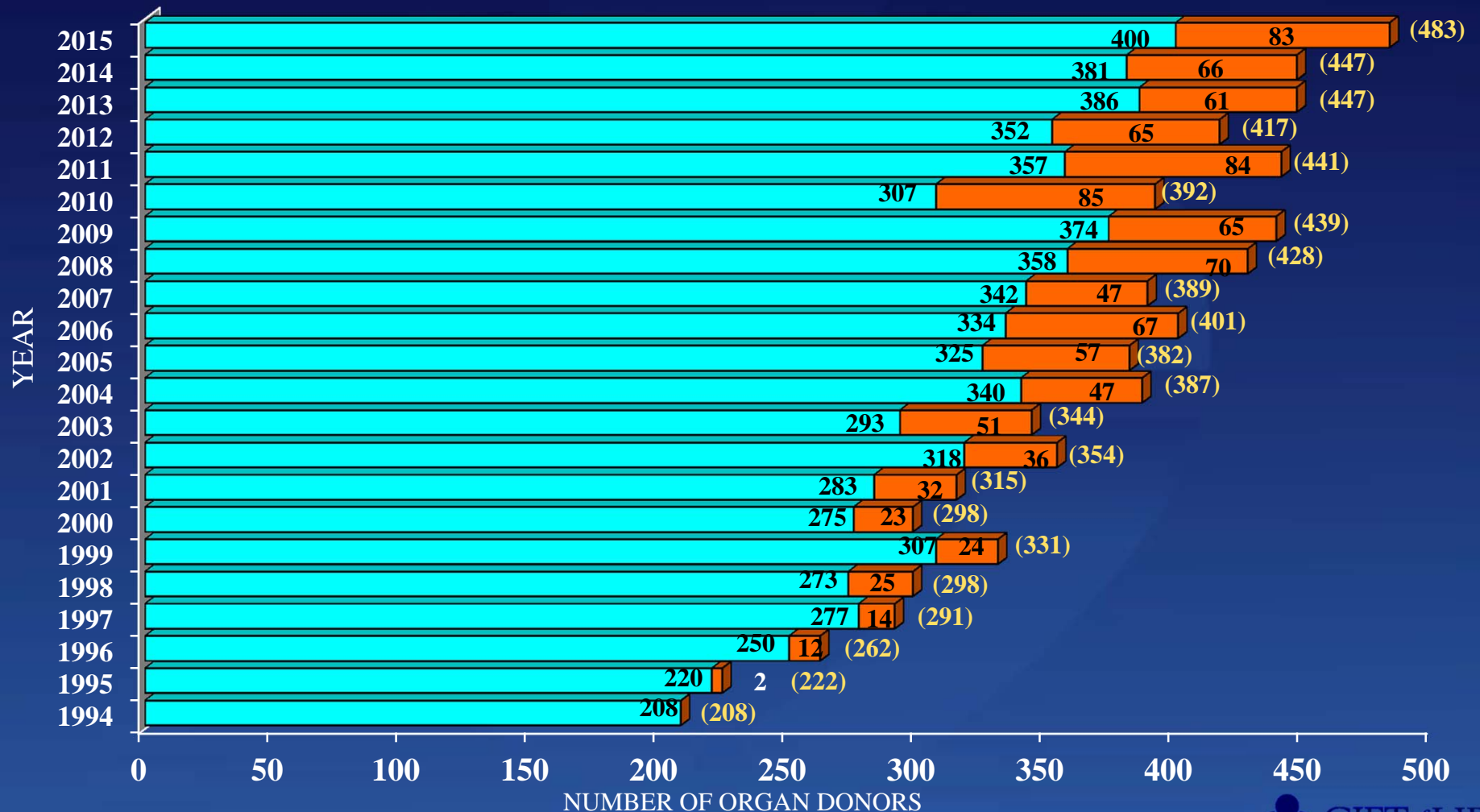
Organ Donor Experience – BD vs. DCD Donors

1994 – 2015

Total Donors = 7,976

■ BD (n=6,960)

■ DCDs (n=1,016)



Source: Based on Gift of Life Donor Program data through December 31, 2015.

Gift of Life: Potential Organ Donor PATHWAYS

ROUTINE REFERRAL All Vent-Dependent

Patients With A Non-Recoverable Neurological Injury

*Donation after
Brain Death*

**Neuro
Exam**

*Donation after
Cardiac Death*

- Exam consistent with brain death
- Support family through grave prognosis
- Death determined by neuro criteria

- Ensure family understands death has occurred
- Approach family about donation options (GLDP And Care Team)

- Support family through informed decision making process
- Support patient during organ evaluation & allocation

- Patient transferred to OR
- Surgical recovery

- Exam Not consistent with brain death
- Care Team / Family discuss grave prognosis & withdrawal of life sustaining therapies

- Ensure family understands grave prognosis
- Approach family about donation options (GLDP And Care Team)

- Support family through informed decision making process
- Support patient during organ evaluation & allocation

- Patient transferred to OR / Withdrawal of Life Support
- Death determined by cardio-pulmonary criteria
- Surgical recovery



Critical Care Nurse dedicated the April 2006 issue entirely to donation and transplantation.

Clinical Article

Maximizing Organ Donation Opportunities Through Donation After Cardiac Death

*John Edwards, RN, RRT, CPTC
Patti Mulvania, RN, CEN, CPTC
Virginia Robertson
Gweneth George
Richard Hasz, MFS, CPTC
Howard Nathan, CPTC
Anthony D'Alessandro, MD*

Organ transplantation is established therapy for many patients with a variety of end-stage diseases. The survival benefits are remarkable, as are the improvements in quality of life. Unfortunately, the supply of donor organs remains insufficient to meet the need.

Recently, through participation in the breakthrough collaboratives of the Health and Human Resources Administration, organ procurement organizations (OPOs) have become engaged in systems change through application of the principles of con-

tinuous improvement. So-called best practices are being shared by OPOs. This sharing, in turn, has created a level of synergy among OPO professionals and hospitals alike that is having a positive impact on the donor supply (Table 1).

Authors

John Edwards is the clinical administrator for Gift of Life Donor Program in Philadelphia, Pa, overseeing all clinical aspects of organ and tissue recovery, and a faculty member for the Gift of Life Institute, Philadelphia, providing training and mentoring for healthcare organizations nationally.

Patti Mulvania oversees the clinical education program for the Gift of Life Donor Program in Philadelphia and is a faculty member of the Gift of Life Institute, specializing in consent and clinical communication.

Virginia Robertson is the associate director of the Gift of Life Institute in Philadelphia. Formerly, she was the director of hospital services for the Gift of Life Donor Program.

Gweneth George is the director of hospital services for the Gift of Life Donor Program in Philadelphia. She directs a team of nearly 20 hospital development staff accountable for donation performance in 150 acute care hospitals.



Gift of Life Donor Program Patient Referrals & Donation Outcomes 2002 – 2015

YEAR	Organ Donor Referrals	Not Brain Dead Referrals	Organ Donors	DCD Donors (% of total donors)
2002	1,507	375	354	36 (10%)
2003	1,540	440	344	51 (15%)
2004	1,734	508	387	47 (12%)
2005	2,235	637	382	57 (15%)
2006	2,454	723	401	67 (17%)
2007	2,941	743	389	47 (12%)
2008	3,476	924	428	70 (16%)
2009	3,815	1,009	439	65 (15%)
2010	3,768	1,388	392	85 (22%)
2011	4,151	1,763	441	84 (19%)
2012	4,326	2,037	417	65 (16%)
2013	4,453	2,208	447	61 (14%)
2014	4,690	2,509	447	66 (15%)
2015	4,802	2,543	483	83 (17%)
Totals	45,892	17,807	5,751	884 (15%)

Gift of Life Donor Program

DCD Experience: Organs Transplanted

1995 – 2015

	'95	'96	'97	'98	'99	'00	'01	'02	'03	'04	'05	'06	'07	'08	'09	'10	'11	'12	'13	'14	'15	Total
DCD Donors	2	12	14	25	24	23	32	36	51	47	57	67	47	70	65	85	84	65	61	66	83	1,016
Kidneys	4	17	21	37	43	42	50	65	77	72	88	122	83	100	89	142	131	90	99	102	126	1,600
Livers	1	2	3	9	9	9	13	12	12	9	22	16	11	14	8	8	11	7	6	12	10	204
Lung	0	0	0	0	0	0	0	0	0	0	0	0	0	4	2	0	0	2	7	0	3	18
Pancreas	0	0	0	0	0	0	2	0	1	4	4	2	0	0	0	0	0	0	0	0	1	14
Total Organs Transplanted																					1,836	

Source: Based on Gift of Life Donor Program data through December 31, 2015.

Gift of Life Donor Program

Hospital Profile DCD Donors

1995 – 2015



1,016 DCD Cases in **95** Hospitals

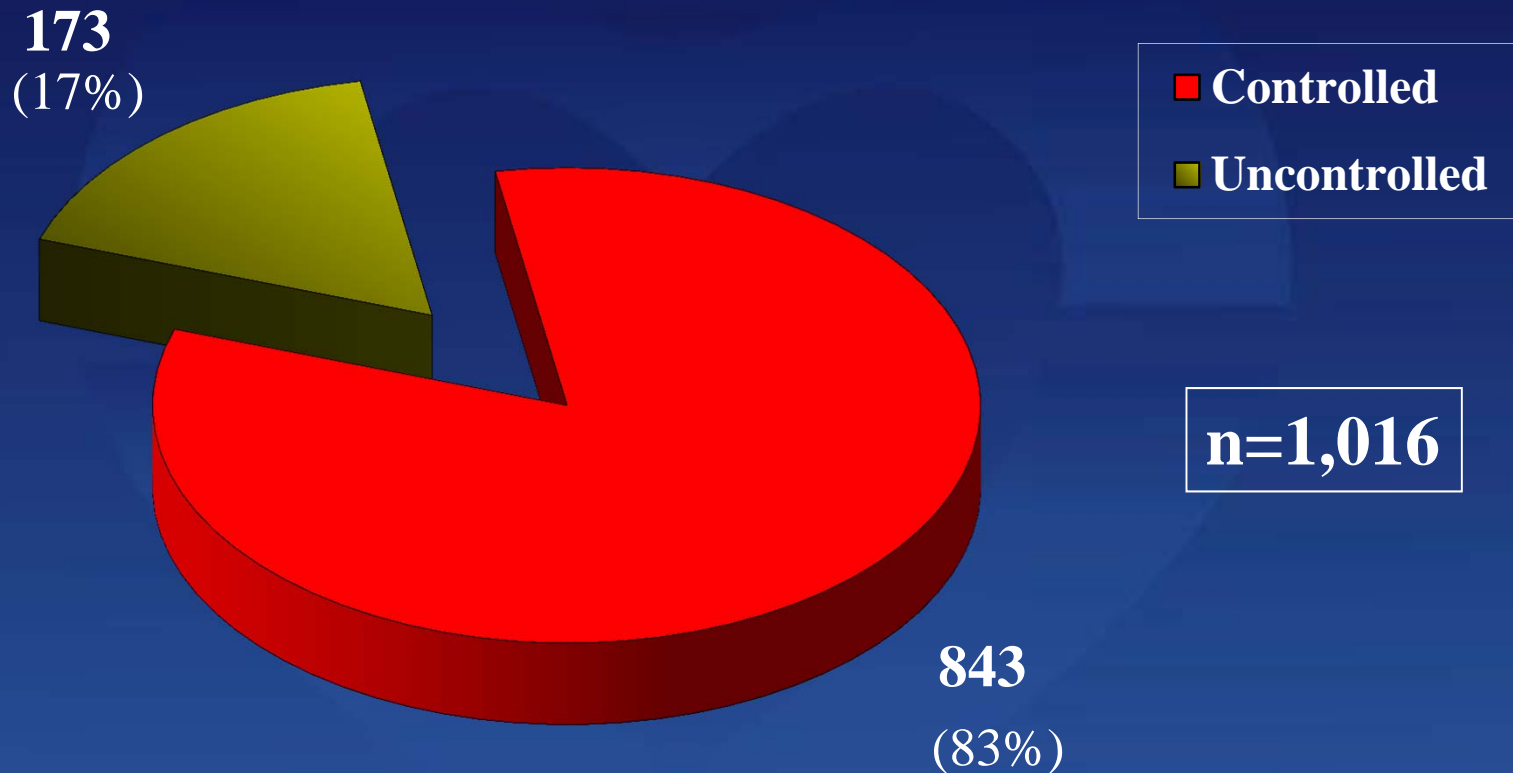
- **15** Transplant Centers
(564 cases – 56%)
- **15** Trauma Centers**
(205 cases – 20%)
- **65** Community Hospitals
(247 cases – 24%)

**Trauma centers only-does not include transplant centers that are also trauma centers.

Source: Based on Gift of Life Donor Program data through December 31, 2015.

Gift of Life Donor Program *DCD Characteristics* 1995 – 2015

Controlled vs. Uncontrolled



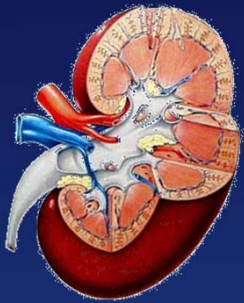
Source: Based on Gift of Life Donor Program data through December 31, 2015.

Gift of Life Donor Program

Uncontrolled DCD Organs Recovered/Transplanted

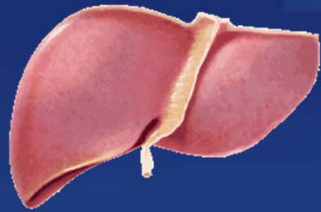
1996 – 2015

Total Uncontrolled DCD Cases = 173



KIDNEY

RECOVERED	338
TRANSPLANTED	224 (66%)



LIVER

RECOVERED	40
TRANSPLANTED	12 (30%)



PANCREAS

RECOVERED	3
TRANSPLANTED	2 (67%)

Source: Based on Gift of Life Donor Program data through December 31, 2015.

Gift of Life Donor Program

Uncontrolled DCD Demographics

1996 – 2015

Total Uncontrolled DCD Cases = 173

Age - 6 months - 76 years; Mean = 32 years

WIT** - 2 to 214 Minutes; Mean = 48 minutes

Gender - Male – 111 (64%) Female – 62 (36%)

Cause of Death -	Trauma	89 (51%)
	Anoxia	55 (32%)
	CVA	25 (15%)
	Other	4 (2%)

Source: Based on Gift of Life Donor Program data through December 31, 2015.

** WIT is defined by GLDP as time removed from the ventilator to aortic cross clamp.

What Do We Evaluate to Determine DCD Potential ?

Organ Function

Secretions

Work of Breathing

Length of Time Patient On Vent

Care/Comfort

Patient's Physical Attributes

Patient's Stated Wish to Donate

• Donor Designation, Conversation w/family, etc.

Family's Commitment to Process

Patient Assessment

For Determination of DCD Suitability

Key Aspects:

- Physician approval (mandatory)
- Determine level of sedation
- Note type of airway (ETT vs. Tracheostomy)
- Note facial trauma, neck / tongue size, secretion production

With appropriate care giving team members present, remove pt. from ventilator

Observe and Measure the following:

- Respiratory Rate
- Tidal Volume
- Minute Ventilation
- Negative Inspiratory Force (NIF)
- Changes in Hemodynamics & Oxygen Saturation
- Length of Time off Ventilator

Respiratory Assessment may be performed at different times during the evaluation process based on the patient's condition and family and care giving team's decision-making process

Respiratory Assessment should **NOT** be performed in certain situations, examples are:

- Profound hemodynamic instability
- Severe pulmonary injury (i.e. ARDS)
- Patient actively receiving paralytics
- High level spinal cord injury
- Significant dependence on maximal ventilatory support
- Complete dependence on some type of mechanical device (i.e. ECMO, RVAD, LVAD, BiVAD,)

The Critical Care Team independently determines comfort care administration and airway removal. The OPO/Transplant team cannot participate in these decisions.

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Additional Factors in DCD Suitability

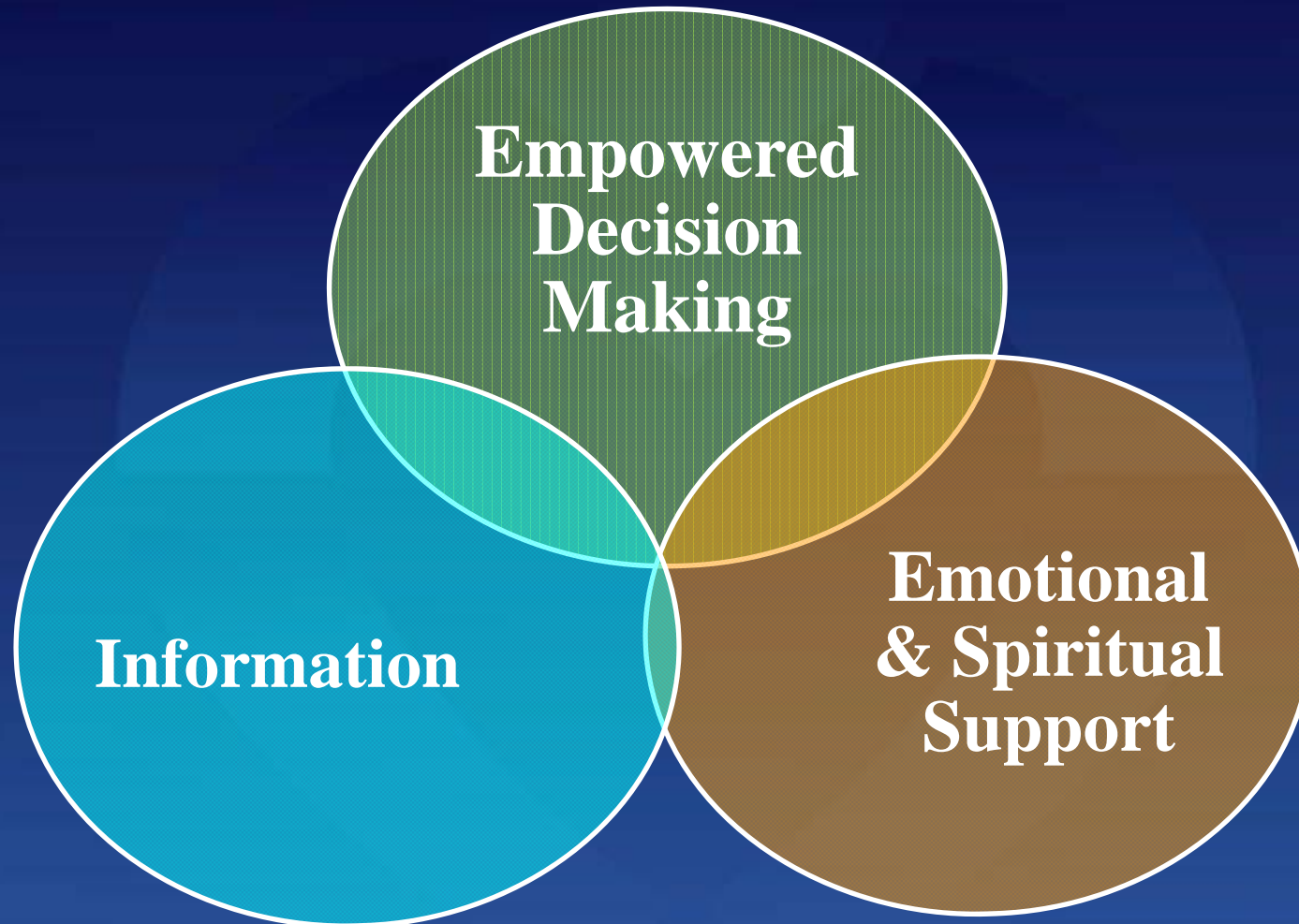
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Clinical Considerations: *Family Discussion*

Decision to
Withdraw
Support

Decision to
Donate Organs

Family Communication: What Families Want, and Need to Know



Clinical Considerations: *Family Discussion*

Considerations for Informed Consent

Heparin
administration

Organs may be
unsuitable for
transplant

Family
presence in the
OR

Patient may
not arrest
within required
timeframe for
donation

Note: A separate consent is required for any invasive procedure



...determination of death will be made and the time of death will be recorded in the medical record.

...donation of organs and/or tissues will occur after artificial support has been discontinued and determination of death has been made.

...actual time until death occurs is variable, and if extended, may preclude organ donation.

...care and comfort measures will be guided by the hospital's care giving team and that heparin will be administered prior to the discontinuation of artificial support for the purpose of supporting organ recovery.

Change of Location: ICU vs. OR

Emphasis on change of location,
not change of withdrawal process

Timing of recovery following
withdrawal and determination of
death

Importance of ischemic time as it
relates to organ viability and
recipient survival

DCD Clinical Considerations:

Family in Attendance at the Withdrawal

Determine who and how many people will be attending the withdrawal

Communicate the process

Determine if the family has any special requirements

Review prepping and draping

Describe each person's role(s).....If the pronouncing physician is different from the attending, make sure you introduce both physicians to the family

Review instrumentation with staff/recovery team, then cover with sterile drapes and back away from OR stretcher

Prepare room for family to go to following the death

Determine how long the family is going to remain at the hospital following the death

Post a sign in the OR that a family is present!

DCD Clinical Considerations

Pronouncement of Death



Attending Physician pronounces death via cardiopulmonary criteria



Transplant team **NOT** permitted in OR until death has been pronounced



INSTITUTE OF MEDICINE

IOM guidelines are followed
(5 minute waiting period)



If patient does not die in timeframe that allows for successful organ recovery, the patient is returned to pre-determined area and comfort care / family support will be continued.

DCD Clinical Considerations: *Organ Allocation*



- DCD organs should be allocated per UNOS or local governing body guidelines
- All organs, including thoracic organs (*if the patient is an appropriate candidate*) should be attempted to be allocated
- Efforts should be made to expedite testing such as tissue typing to reduce cold ischemic time

DCD Clinical Considerations: *If the Patient Does Not Die...Next Steps*

- Re-admission to ICU or med-surg
- Attending physician
- Continued care and comfort
- DNR
- Support system for family
- According to pre-determined plan



Are Medical Professionals Hastening the Death of the Patient With DCD?

- Patients considered for DCD have suffered an irreversible, catastrophic brain injury or other end-stage condition.
- Family members – in consultation with the patient's physician – decide whether life support should be withdrawn.
- The decision to withdraw life support and the decision to donate organs are *independent* of one another.

The Supply of Controlled DCDs in the United States

Halpern, SD, Hasz, R. et al

JAMA, December 15, 2010—Vol 304, No. 23

- Retrospective review of death records in 50 large hospitals in Gift of Life region (trauma centers and/or > 20 ICU beds)

Patients removed from vent and died within 120 minutes

Medically suitable for donation of at least one organ

Estimated 3,200 to 4,700 potential DCDs (controlled) in the U.S.

JAMA

The Journal of the American Medical Association

RESEARCH LETTER

Estimated Supply of Organ Donors After Circulatory Determination of Death: A Population-Based Cohort Study

To the Editor: Increased use of donors after circulatory determination of death (DCDD) has been advocated as the most viable method for increasing the supply of transplantable organs.¹ However, the number of potential DCDD in the United States remains uncertain, with estimates accruing from retrospective single-center experiences in adult^{2,3} or pediatric^{4,5} hospitals. We conducted a prospective, population-based cohort study to estimate the potential increase in the supply of deceased donors that might accrue from optimal use of *controlled DCDD*, donors in whom life-sustaining therapies are withdrawn and organs are recovered following the loss of spontane

Table 1. Criteria for Defining Potential DCDD^a

	Kidney	Liver	Pancreas	Lung
Optimal (all are required)	Time to death ≤ 60 min Age ≤ 50 y	Time to death ≤ 30 min Age ≤ 45 y (age ≤ 40 y if stroke is COD) Tbili ≤ 2 mg/dL ALT and AST ≤ 100 U/L	Time to death ≤ 30 min Age ≤ 35 y	Time to death ≤ 60 min Age ≤ 55 y P-F ratio ≤ 300 Clear chest radiograph
Suboptimal (any one is sufficient)	Time to death 60-90 min Age 51-70 y BMI > 35 History of diabetes ≥ 2 of following: stroke as COD, or > 1.5 mg/dL, history of hypertension	Time to death 31-60 min Age 46-60 y BMI > 30 Na ≤ 155 mmol/L, or stroke as COD but not both Tbili > 2.1 mg/dL ALT or AST > 101 U/L	Time to death 31-45 min Age 36-45 y	Time to death 60-90 min Age 56-60 y Smoking history > 20 pack-years P-F ratio 200-300 Chest radiograph showing infiltrate, atelectasis, or edema History of cardiac disease
Ineligible (any one is sufficient)	History of chronic kidney disease Use of renal replacement therapy while in ICU Cr > 2.5 mg/dL plus UOP < 0.75 mL/4h	Age > 60 y BMI > 40 Time to death > 60 min Both Na ≤ 155 mmol/L and stroke as COD History of acute or chronic liver disease Tbili > 3 mg/dL ALT or AST > 300 U/L	Time to death > 45 min Age > 45 y BMI > 30 History of diabetes, pancreatic disease, or alcohol abuse	Age > 60 y History of chronic lung disease P-F ratio < 200 > 1 Abnormality on chest radiograph

Abbreviations: ALT, serum aminotransferase; AST, aspartate aminotransferase; BMI, body mass index (calculated as weight in kilograms squared by height in meters squared); COD, cause of death; Cr, serum creatinine; DCDD, donor after circulatory determination of death; ICU, intensive care unit; Na, sodium; P-F ratio, ratio of PaO₂ to fraction of inspired oxygen (FIO₂); Tbil, total bilirubin; UOP, urine output during first 6 hours of life.

^a Conversion factors: To convert ALT and AST to $\mu\text{mol/L}$, multiply by 0.167; Cr to $\mu\text{mol/L}$, multiply by 88.4; and Tbil to $\mu\text{mol/L}$, multiply by 17.104.

^b Time to death refers to minutes elapsing between withdrawal of the final life-sustaining therapy and declaration of death.

NYDN Home - Collections -> **Organ Donation**

New organ donation test project includes those who die at home; could be boon for transplants

BY HEDI EVANS
 DAILY NEWS STAFF WRITER
 Thursday, August 12, 2010

A groundbreaking program that could increase the number of organ donors in New York - and potentially the nation - has cleared a final hurdle, the Daily News has learned.

The six-month test project, which could begin this fall, will allow doctors to approach families within 20 minutes after a loved one dies of cardiac arrest at home - a first in the country.

Currently in the U.S., only people who have died in a hospital are eligible for organ donation. But 95% of cardiac deaths occur at home - or at work or even walking down the street.

"This is a remarkable opportunity for those on the waitlist for organ donation and those who wished to donate before they died," said Dr. Lewis Goldfrank, who spearheaded the three-year effort and is chairman of emergency medicine at NYU and Bellevue Hospital.

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ORGAN DONATION

New York testing 2-team approach to boost organ donation

December 01, 2010 | By David Ariosto, CNN

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Some 911 calls that involve cardiac arrest or stroke could bring a second emergency crew to the scene as part of a pilot program in New York intended to more quickly recover organs from potential donors, the mayor said Wednesday.

When efforts by the first ambulance teams to save patients' lives fail and if the victims are registered organ donors, a newly created dispatch unit monitoring emergency calls will instruct secondary crews -- called Organ Preservation Units -- to bring the victims to a medical center where their kidneys can be recovered, according to New York Mayor Michael Bloomberg.

Under the program, only kidneys can be recovered from deceased individuals who die from cardiac arrest or stroke.

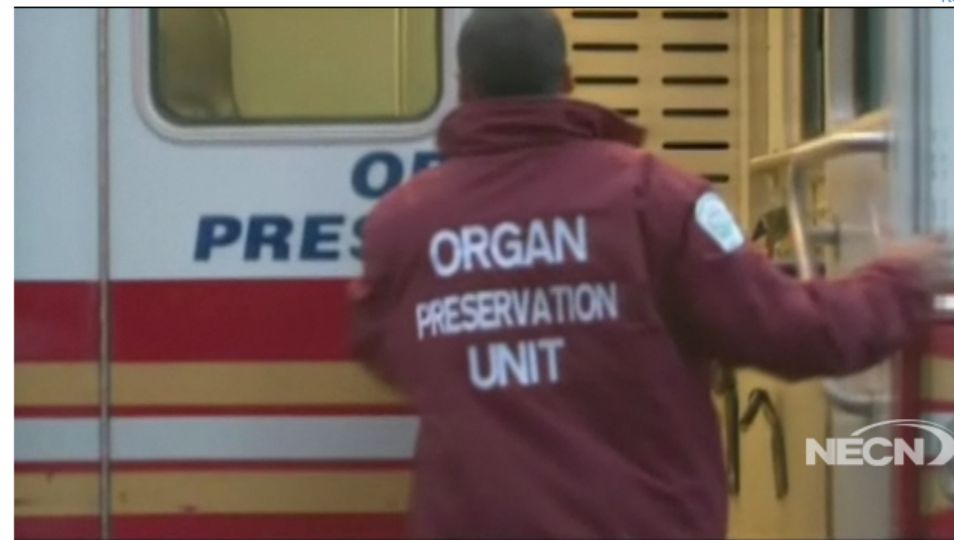
In hopes of ultimately narrowing the gap between the supply and demand of organs for transplantation, a pilot project in New York City is looking to a group of individuals who currently aren't eligible to donate in the United States—those who die of a cardiac cause at home.

“As the Institute of Medicine suggested, even using restrictive criteria of people whose kidneys would be adequate, there might be 20,000 people easily available in America were we to develop a system.”

NYC program may help thousands waiting for organ transplants

Dec 4, 2010 9:01pm

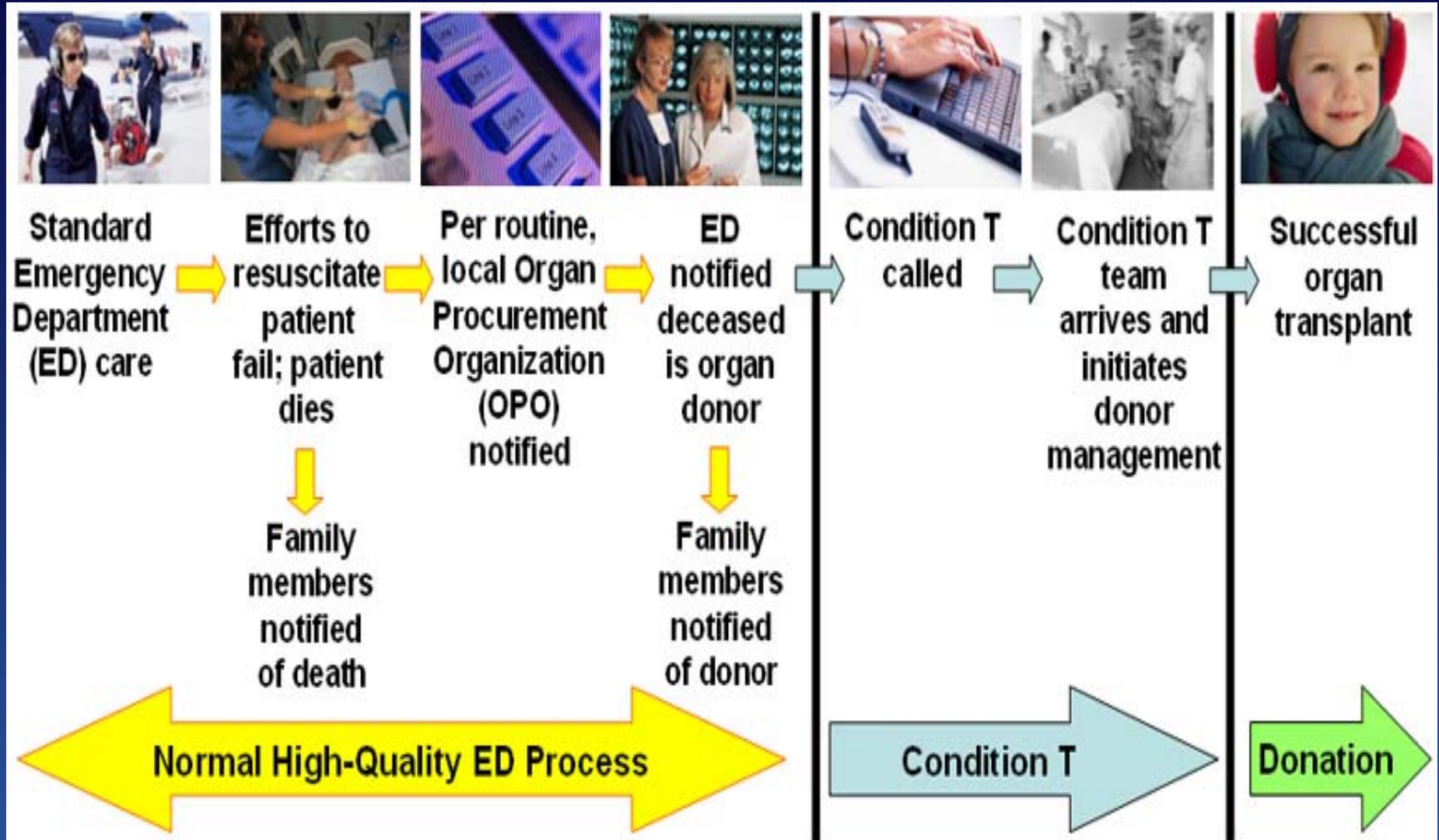
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NYC program may help thousands waiting for organ transplants

Organ preservation units follow ambulances to cardiac arrest calls

Pittsburgh Condition T Rapid Recovery Protocol



Summary of DCDs in the U.S.

- 16 % of organ donors in 2015
- 57 of 58 OPOs recovered DCDs (2015)
- Extensive literature on DCD protocols
- Most hospitals have DCD policies
- Transplant outcomes comparable to DBDs
- Uncontrolled DCDs/Rapid Recovery in some OPOs
- DCDs could increase donor pool significantly and reduce deaths on the wait list



CASE STUDIES

Patient Presentation - 2007

28 y/o Male police officer hit by bus with traumatic brain injury, pulmonary contusions

Patient was intubated in ER and started on pressors, hespan

Initial head CT revealed SAH, SDH with midline shift

4 hours after admission to ICU, patient was referred to Gift of Life Donor Program (GLDP)

Clinical Presentation

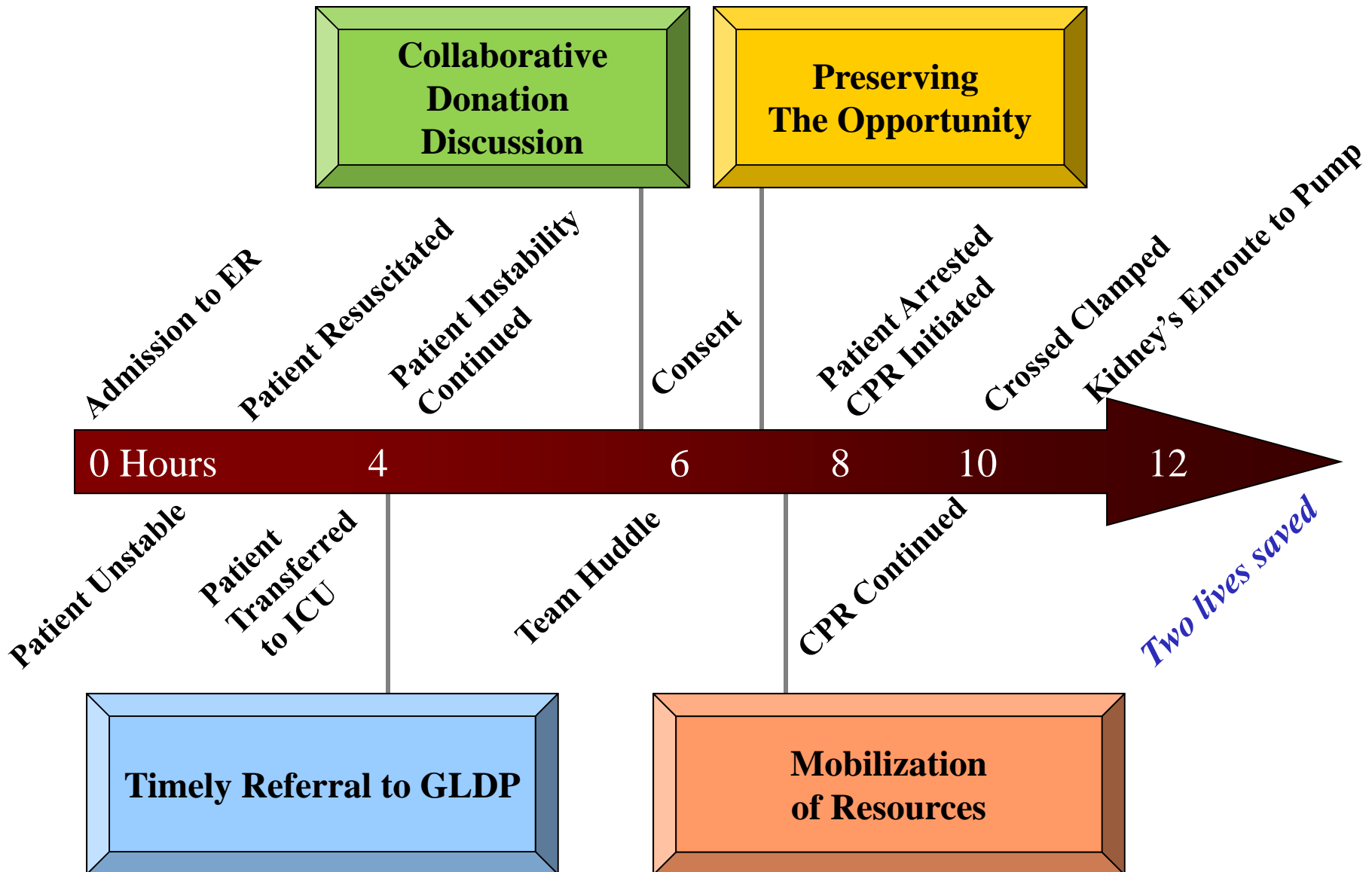
Patient unstable upon GLDP Transplant Coordinator (TC) arrival on ICU

Patient on maximum pressor support with BP in low 50's; continuing to hemorrhage from head wounds

Patient's wife decided to maintain current course of treatment short of "heroic measures"

GLDP TC partnered with care team for early family approach prior to pronouncement of death to preserve the family's opportunity for donation

Uncontrolled DCD Timeline



Kidney Recovery Data

Warm Ischemic Time

144 minutes (time from w/d to cross-clamp)

Biopsy

- Right Kidney 51 glomeruli with 5% sclerosed
- Left Kidney 41 glomeruli with 2% sclerosed



Pulsatile Preservation Results

Right Kidney:

- Flow of 120 cc/min and resistance of 0.24

Left Kidney:

- Flow of 125 cc/min and resistance of 0.23



Outcomes

Right Kidney:

Transplanted into a 37 y/o male with five children.

He had been waiting for a life-saving transplant for three years.

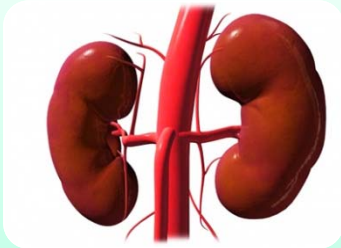
Left Kidney:

Transplanted into a 41 y/o male with one child.

He had been waiting for over three years for a transplant.



Summary



Kidneys can be successfully recovered and transplanted from uncontrolled DCD donors.



Families need to be informed of the necessity of chest compressions to preserve the opportunity for donation.



Organ procurement organizations (OPOs) should consider developing protocols to address uncontrolled DCD in their donation service area to increase the number of organs available for transplantation.



Extraordinary DCD Cases



Case Study: DCD Organ Donor AICU

- Patient JM: 58 year-old Caucasian Female
- Past Medical Hx: ALS, on Bipap, patient reaches out to Gift of Life and signs consent on 1/4; Regional hospital ICU attending physician and staff made aware by GOL team ahead of time
- 2/12: Patient experiences respiratory distress and is admitted to ED and then ICU and placed on vent in order to be a Donor after Cardiac Death (DCD), as per patient's wishes
- Attending ICU physician and several nurses from the ICU support patient and take patient to OR for DCD donation process
- 2/13: Patient donates both of her kidneys after cardiac death, one of which goes to the patient's cousin

A mother's plea to fulfill both of her
daughter's end-of-life wishes:

The patient was donor designated
and

had also made the request that should she die,
she wanted her service dog of many years by
her side during the process.



Recovery

- The family and service dog were dressed appropriately for the OR.
- Family and the service dog were escorted to patient's side for extubation.
- Death was determined 15 minutes later



Wishes Fulfilled



- Upon asystole, the dog who had been lying calm throughout the process, stood up and put his head under her hand.
- Both kidneys were transplanted with 27 minutes of warm ischemic time. The liver was placed for research.

OUR **TODAY**, THEIR **TOMORROW**:

Rewriting
the
stories...



THANK YOU!

*Questions?
More Information?*

Howard M. Nathan

hnathan@donors1.org

