OPTN Deceased Donor Potential Study
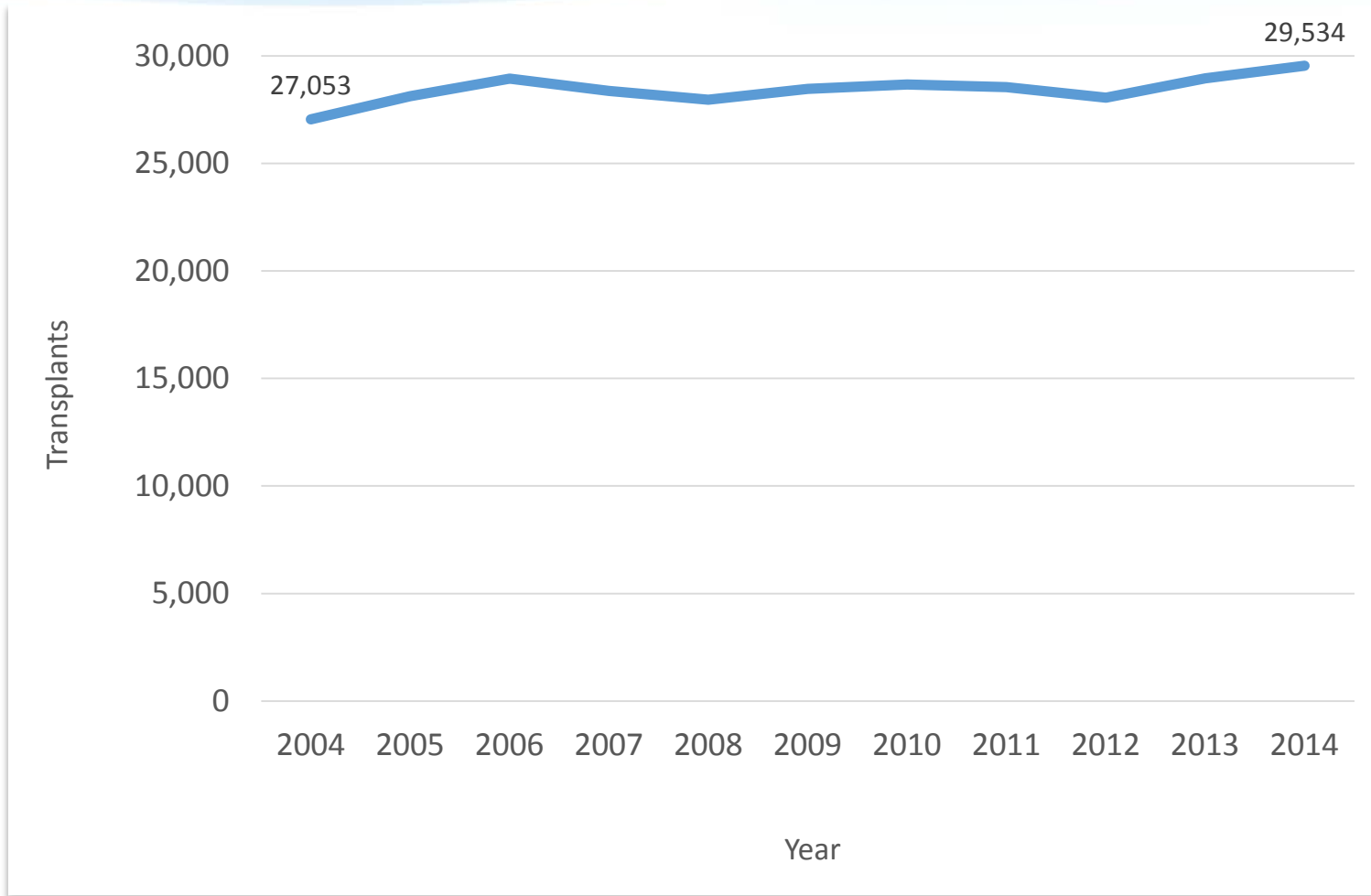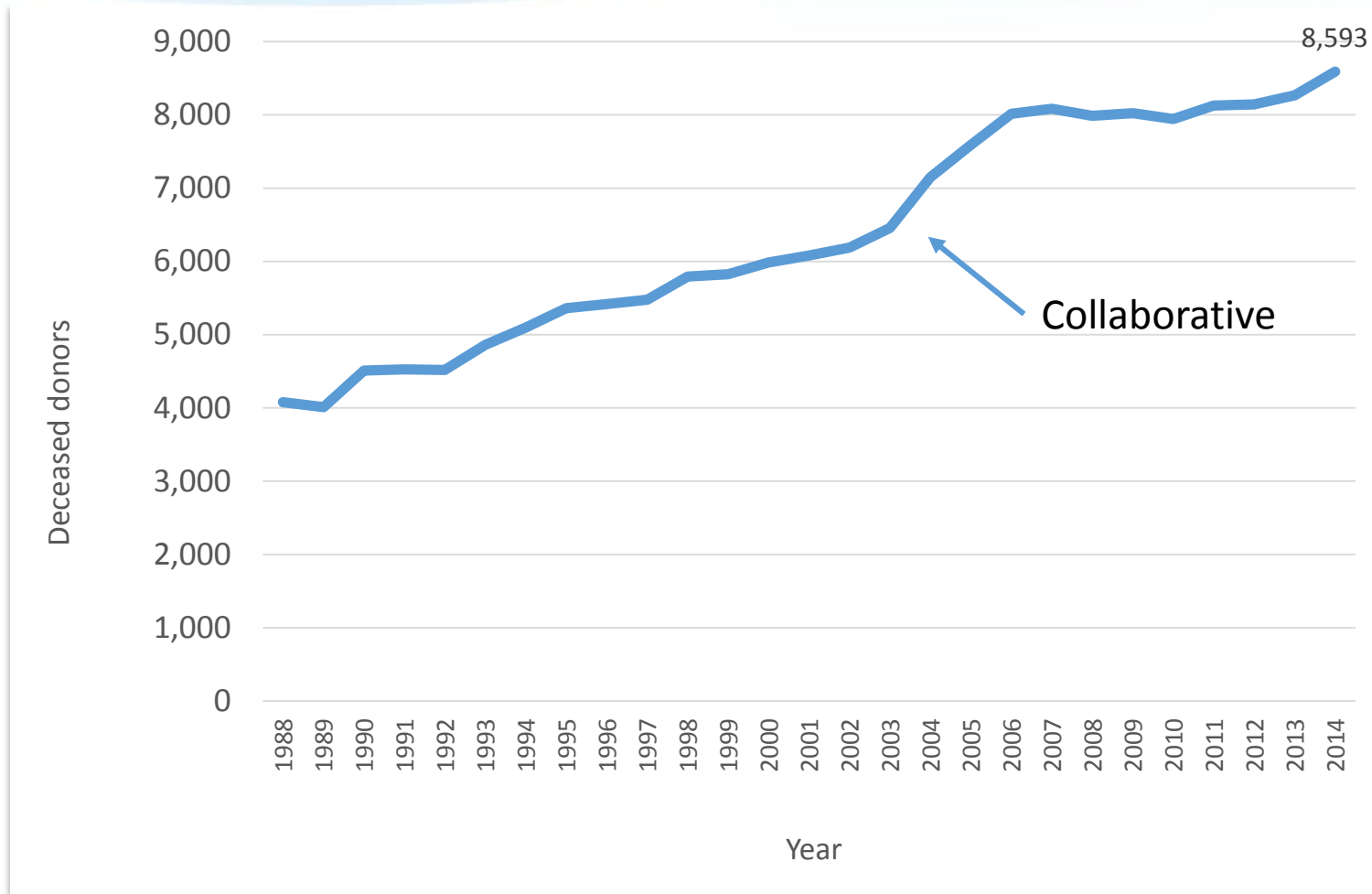# Advisory Committee on Organ Transplantation
March 12-13, 2015

David Klassen, MD

UNOS Chief Medical Officer

Total number of transplants

Deceased donors recovered in the U.S. 1988-2012

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Deceased Donor Potential Study

- Proposed by HRSA in July 2010, preliminary data analysis completed in mid 2013

- DDPS work group: 52 members, extensive skill sets, multiple disciplines and stakeholders represented

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Deceased Donor Potential Study goals

- Accurately characterize the size and composition of the potential donor pool

- Predict the donor potential changes over 5-10 years

- Provide a foundation for national goals and policy development

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Major DDPS Findings

- Significant donor potential exists: DDPS estimate 37,000 potential donors per year

- Majority of unrealized donor potential resides in an older donor population (>70% in 50-75 year old population)

- Projects minimal growth of donor potential through 2020: 0.5% per year

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How were these results obtained? What do they mean?

- Study design

- Assumptions underlying study design

- Methods and data sources

- Database limitations

- Implications for policy, practice, and research

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Sluicing for gold
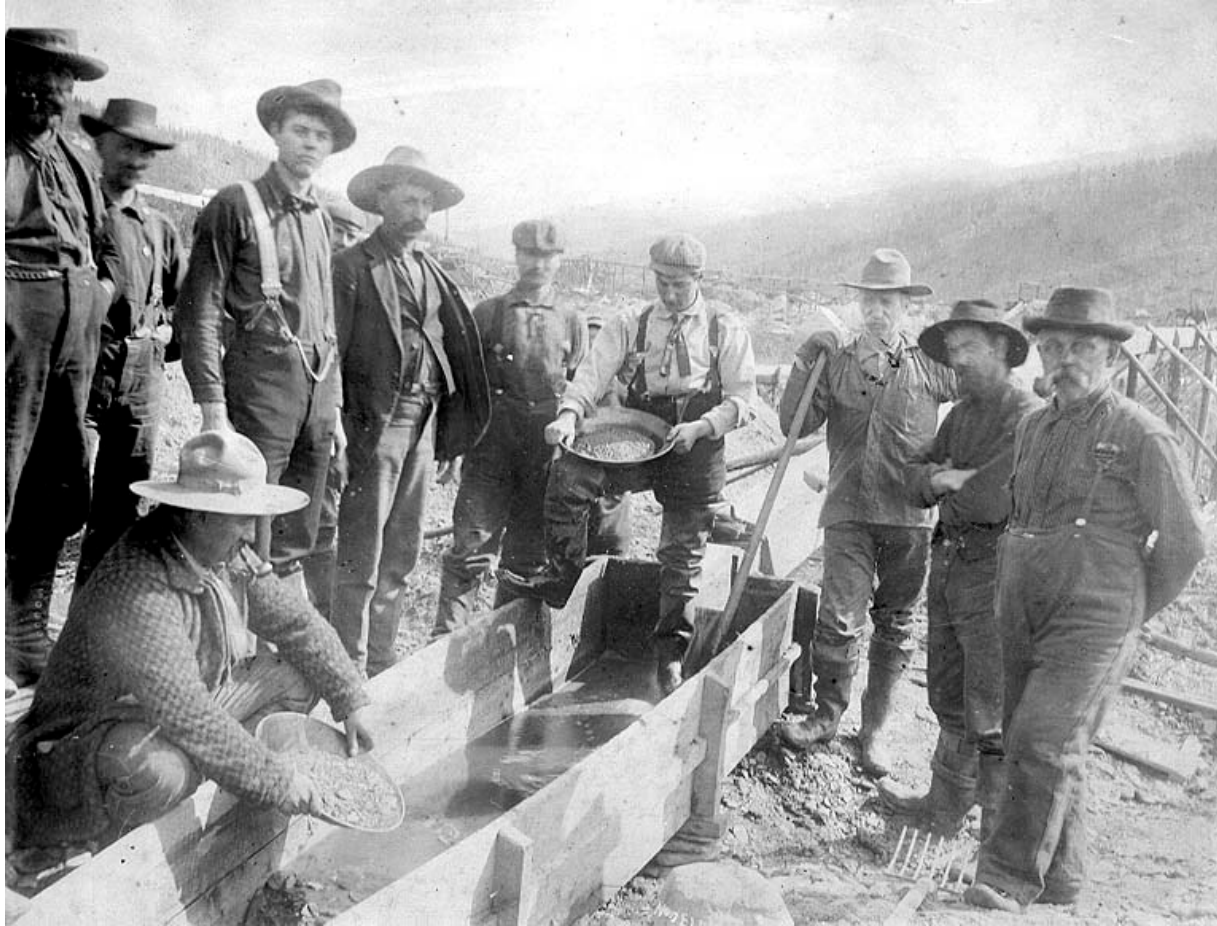
DDPS analytic approach

- Apply "filtering" strategies to national death and hospitalization data sets

- Two independent subcommittees using different data sets and assumptions produced size estimates and characteristics of donor potential

- Regression modeling of trends in the potentials derived from the filtered estimates was used to extrapolate future growth

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Data sources: CDC-NCHS Multiple Cause Mortality File

- Contains records on 99% of all deaths in the US from 2000-present

- Mortality data derived from death certificates completed by funeral directors, physicians, medical examiners

- Contains primary cause of death an up to 20 additional causes, coded by ICD-10

- **Data limitations**: Clinical information limited to cause of death. Limited information on co-morbidities, procedures, and hospitalization status at time of death. ICD-10 cause of death mapped to OPTN data system is not direct and may result in inaccuracy. Likely overestimation of potential if used as sole source of data. Overestimation not possible to quantify without direct chart review.

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Data sources: AHRQ Nationwide Inpatient Sample

- Largest all-payer inpatient data set in US

- 20% stratified sample of US community hospitals that comprise 95% of all hospital discharges; 8 million per year

- Contains severity adjustment data elements, disease staging, and AHRQ co-morbidity indicators. Uses ICD-9 codes. Allows linkage to American Hospital Association Annual Survey Database and Area Resource Files

- 1988-present; large sample size allows analysis of rare conditions

- **Data limitations**: only basic demographic data (age, gender, ethnicity). Does not contain lab data, serology, or measures of organ function. Dependent on accuracy of reporting of diagnosis and procedure codes. Coding practice may change over time
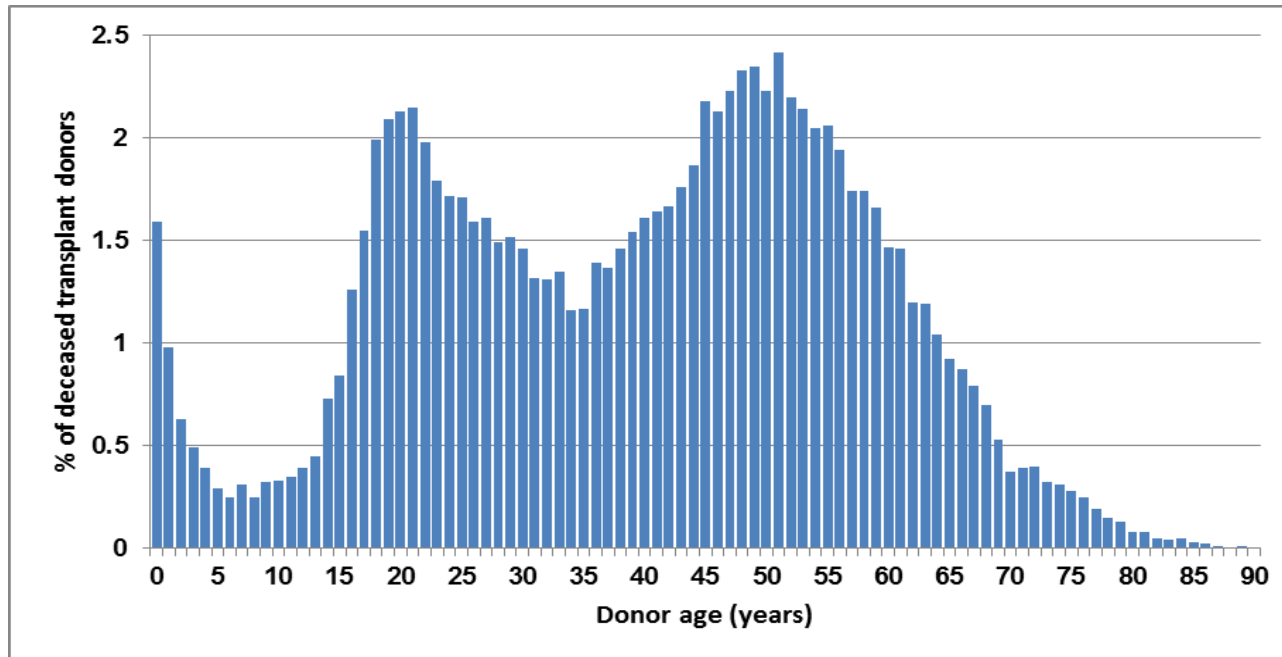
Data sources: OPTN data

- Includes every deceased donor from 1988 to the present

- Contains medical history, demographic data, lab values, serology, medications, organ specific tests, social history

- OPO reported person-level data on imminent and eligible deaths defined by OPTN policy 1.2 (exclusions by age, infection, malignancy, diagnosis etc.)

- Useful to define the characteristics of confirmed donor cases

- Imminent and eligible data may be useful to account for gaps between the estimated number of potential donors and the actual number of donors

- **Data limitations**: imminent and eligible death definitions are not inclusive of all potential donors. They were developed as a standard measure of OPO performance rather than to capture all donor potential.

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Methods: OPO filtering strategy

- **OPO subcommittee**: Survey of OPO personnel regarding relative and absolute donor exclusionary criteria used to filter data. Assessed age limits, clinical and behavioral/social history. Survey based primarily on eligible death definition (OPTN policy 1.2), PHS guidelines, and OPTN data

- Filter applied to NCHS multiple cause mortality file.

- Similar results for DBD and DCD donation

- Includes inclusionary and exclusionary criteria

- **Limitations**: Not all criteria available in NCHS data. Ventilation rate from NIS stratified by age, year of death, cause of death, diagnosis. Projections based on current donor definition. Potential for over estimation.

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Age distribution deceased donors 2008-2012

OPO NCHS filter

Stage 0: All U.S. Deaths 2000-2010

Stage 1: Limit based on age

Stage 2: Additionally limit to deaths occurring in-hospital

Stage 3: Additionally limit by excluding COD within ICD-10 exclusionary codes

Stage 4: Additionally limit by including COD in ICD-10 codes associated with donation

Stage 5: Apply ventilated percentages

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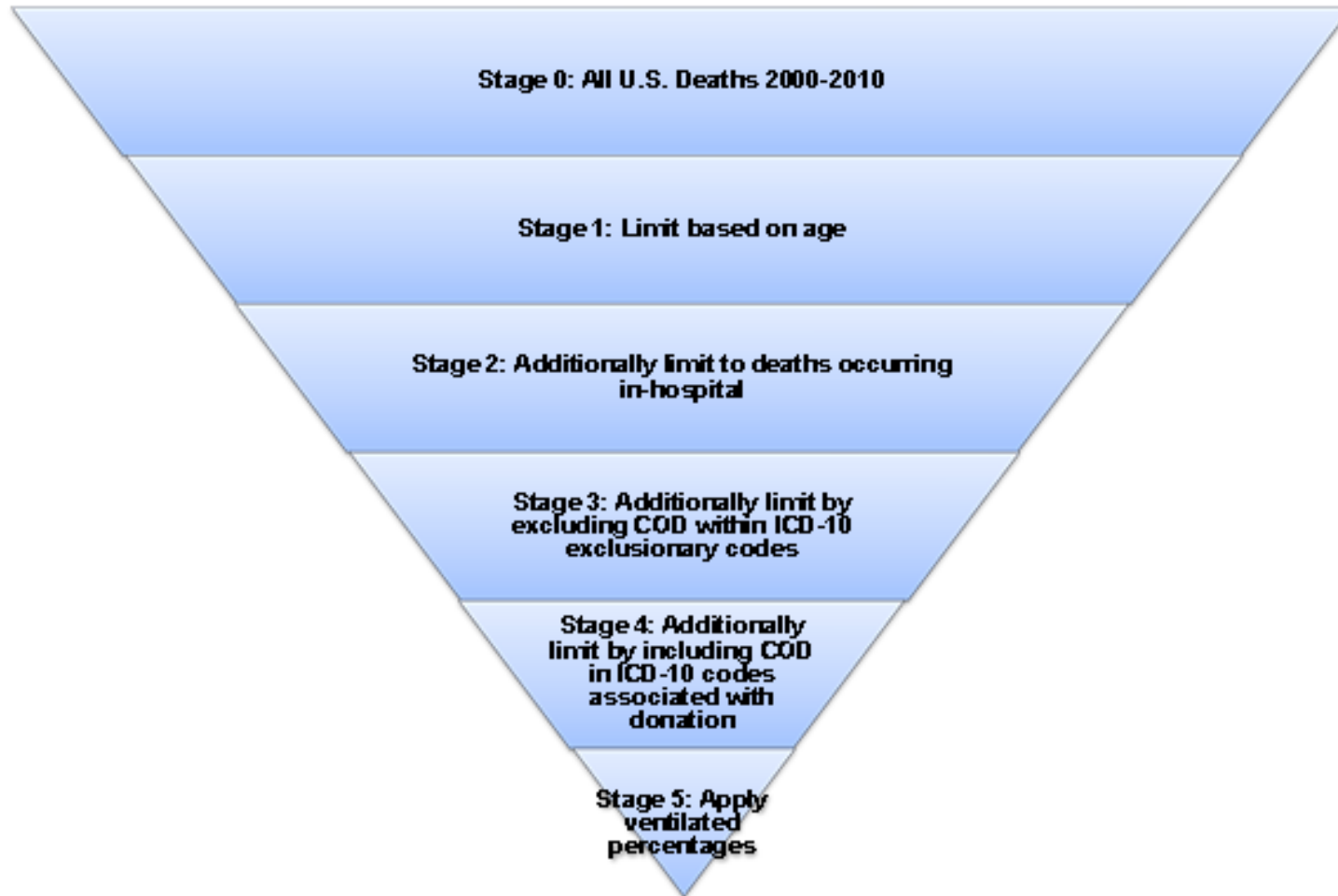
Methods: CIG filtering strategy

- **Caregiver Informant Group subcommittee**: Alternative approach to "eligible death" criteria

- Principle 1; potential donor should not have a condition that would preclude organ function.

- Principle 2; potential donor should not have a condition that would place recipient at risk

- Criteria: mechanical ventilation, lack of metastatic cancer, lack of sepsis/MSOF, diagnosis predictive of brain death.

- Sensitivity matrix using hospital length of stay and severity of illness scoring

- "Eligible death" criteria also analyzed separately

Methods: CIG sensitivity matrix filtering strategy

- Severity of illness points assigned by mapping ICD-9 diagnostic codes to 29 medical conditions associated with severity of illness and mortality risk. Developed by Elixhauser for use with administrative data, modified by van Walraven

- Severity of illness score predicts organ specific exclusionary diagnoses

- 90th percentile cutoff for severity of illness score

- Donor length of stay derived CIG opinion, confirmed by OPTN data of actual donors. Median 3 days, 97th percentile 14 days.

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CIG filter for potential deceased donors applied to 2010 NIS

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┌─────────────────────────────────────┐
│   All 2010 NIS Death Hospitalizations │
│        (sample weighted)              │
│      N=740,748 (100% of deaths)       │
└─────────────────────────────────────┘
                  │
┌─────────────────────────────────────┐
│            Step 1:                    │
│    Deaths where Mechanical            │
│      Ventilation was Used             │
│       N=368,174 (50%)                 │
└─────────────────────────────────────┘
                  │
┌─────────────────────────────────────┐
│            Step 2:                    │
│    Remaining Deaths without           │
│  Malignant or Metastatic Cancer       │
│       N=308,587 (42%)                 │
└─────────────────────────────────────┘
                  │
┌─────────────────────────────────────┐
│            Step 3:                    │
│  Remaining Deaths without Systemic    │
│  Inflammation in Conjunction with     │
│        Organ Dysfunction              │
│       N=218,828 (30%)                 │
│       ("Evaluable Deaths")            │
└─────────────────────────────────────┘
                  │
┌─────────────────────────────────────┐
│            Step 4:                    │
│  Remaining Deaths with Diagnoses      │
│     Associated with Brain             │
│        Death/Donation                 │
│       N=72,150 (10%)                  │
└─────────────────────────────────────┘
                  │
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Step 5: Remaining Deaths with Age<=90 N=69,332 (9%)		Length of Stay		
Age	Severity of Illness Score	<=3	<=14	Any
0-75	<=18	24,638	38,292	42,436
	Any	25,474	40,835	46,030
0-85	<=18	32,846	51,979	57,816
	Any	33,991	55,604	62,928
0-90	<=18	35,981	57,222	63,590
	Any	37,301	61,360	69,332

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Characterization of potential donor pool

- Distribution of age, length of stay, severity of illness, number of diagnoses, gender, race analyzed

- Prevalence of Elixhauser comorbidities

- Prevalence of each of the 250+ CCS diagnostic groups, overall and by age group

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Presence of organ-specific, Elixhauser Morbidity Conditions among 2010 NIS cases that passed through DDPS filter (Steps 1-5)

|	Congestive Heart Failure	Chronic Lung Disease	Diabetes	Liver Disease	Pulmonary Circulation Disorders	Renal Failure
Severity of Illness Score (percentile)						
<=0 (0-25%)	0.1%	1.9%	13.6%	0.0%	0.3%	0.3%
1-6 (25-50%)	3.0%	13.5%	18.0%	0.3%	2.4%	7.4%
7-12 (50-75%)	19.8%	19.3%	22.4%	2.2%	5.2%	16.8%
13-18 (75-90%)	35.8%	26.2%	24.2%	6.9%	8.6%	25.6%
19-28 (90-99%)	58.3%	36.3%	24.3%	20.5%	16.9%	41.3%
29+ (99-100%)	78.3%	50.3%	32.1%	45.7%	37.7%	56.0%
All	16.0%	15.8%	19.4%	3.6%	4.8%	13.5%

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Comparison of estimated potential donors from OPO vs. CIG Analyses

Subcommittee	Data source	Filtered Deaths (Inpatient)
OPO	2010 NCHS	37,258
CIG	2010 NIS	38,292
Difference		1,034 (2.8%)

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OPO estimated deceased donor potential

Year	Stage 0: All deaths	Stage 1: ≤ 75 years	Stage 2: Inpatient	Stage 3: ICD-10 exclusions	Stage 4: ICD-10 inclusions	Stage 5: Vent rates applied
2000	2,407,193	1,110,016	480,358	225,217	59,715	35,679
2001	2,419,960	1,111,535	474,530	225,645	58,035	34,794
2002	2,446,796	1,116,957	470,370	225,460	57,500	35,767
2003	2,452,154	1,118,729	464,442	223,973	55,797	36,316
2004	2,401,400	1,099,222	445,697	218,054	54,213	36,242
2005	2,452,506	1,116,026	444,593	217,785	53,335	36,463
2006	2,430,725	1,112,287	439,251	215,724	52,509	36,485
2007	2,428,343	1,111,602	436,609	214,416	52,947	37,208
2008	2,476,811	1,127,284	433,559	211,712	50,442	36,231
2009	2,441,219	1,126,882	412,918	204,802	47,686	35,615
2010	2,472,542	1,130,036	416,246	205,478	49,087	37,258

# Time trends in deceased transplant donors and estimated potential donors
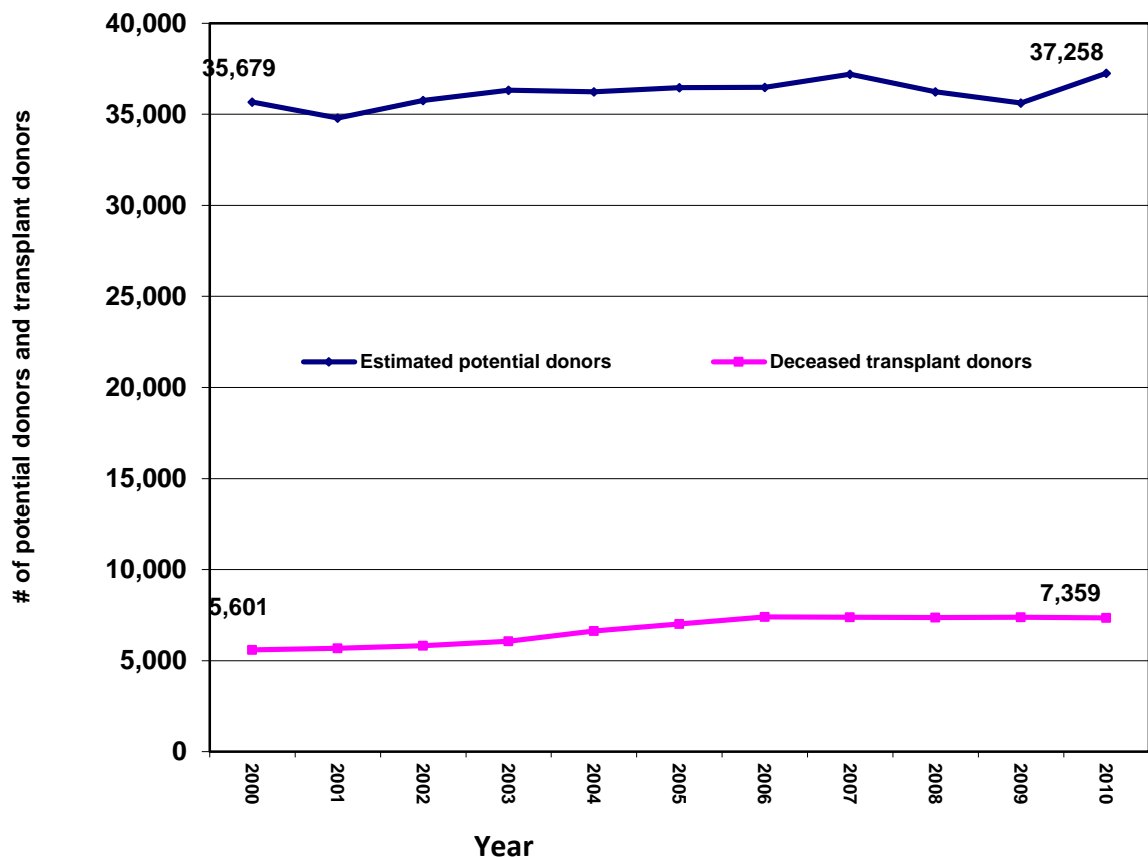
Comparison of age distribution for estimated potential donors and actual transplant donors
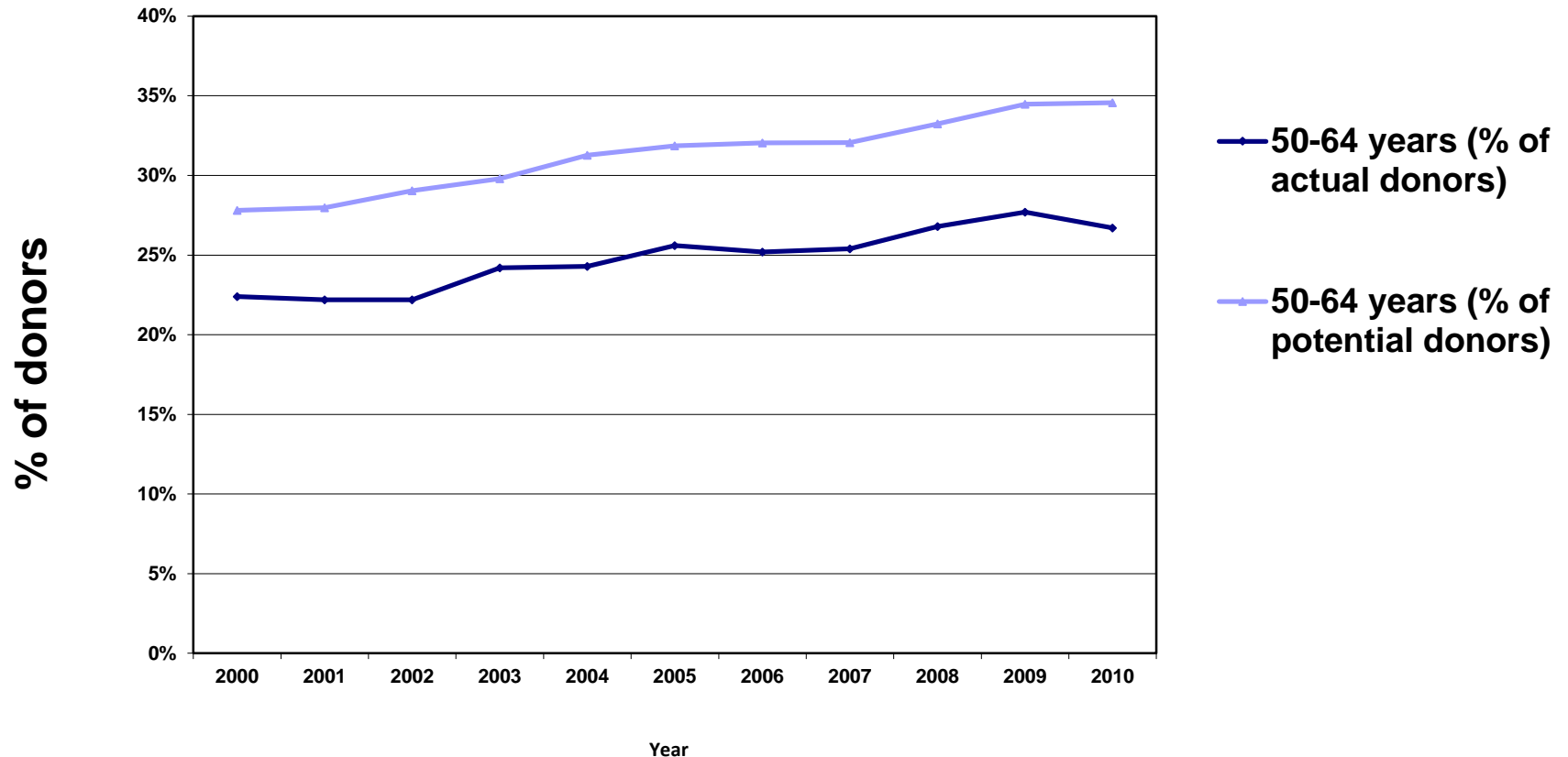
Age distribution of CIG estimated potential donors

Age	Estimated Potential Donors ("cell 2")	Actual Donors w/ Organ(s) Transplanted (per OPTN)	Estimated "Realization Rates" (Actual/ Potential Donors)
<1	504	112	22.2%
1-5	634	191	30.1%
6-10	201	100	49.8%
11-15	808	427	52.8%
18-34	5,052	2,140	42.4%
35-49	6,268	1,961	31.3%
50-64	13,274	1,965	14.8%
65-75	11,552	463	4.0%
All	38,292	7,359	19.2%

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Estimated potential donors and projected potential donors
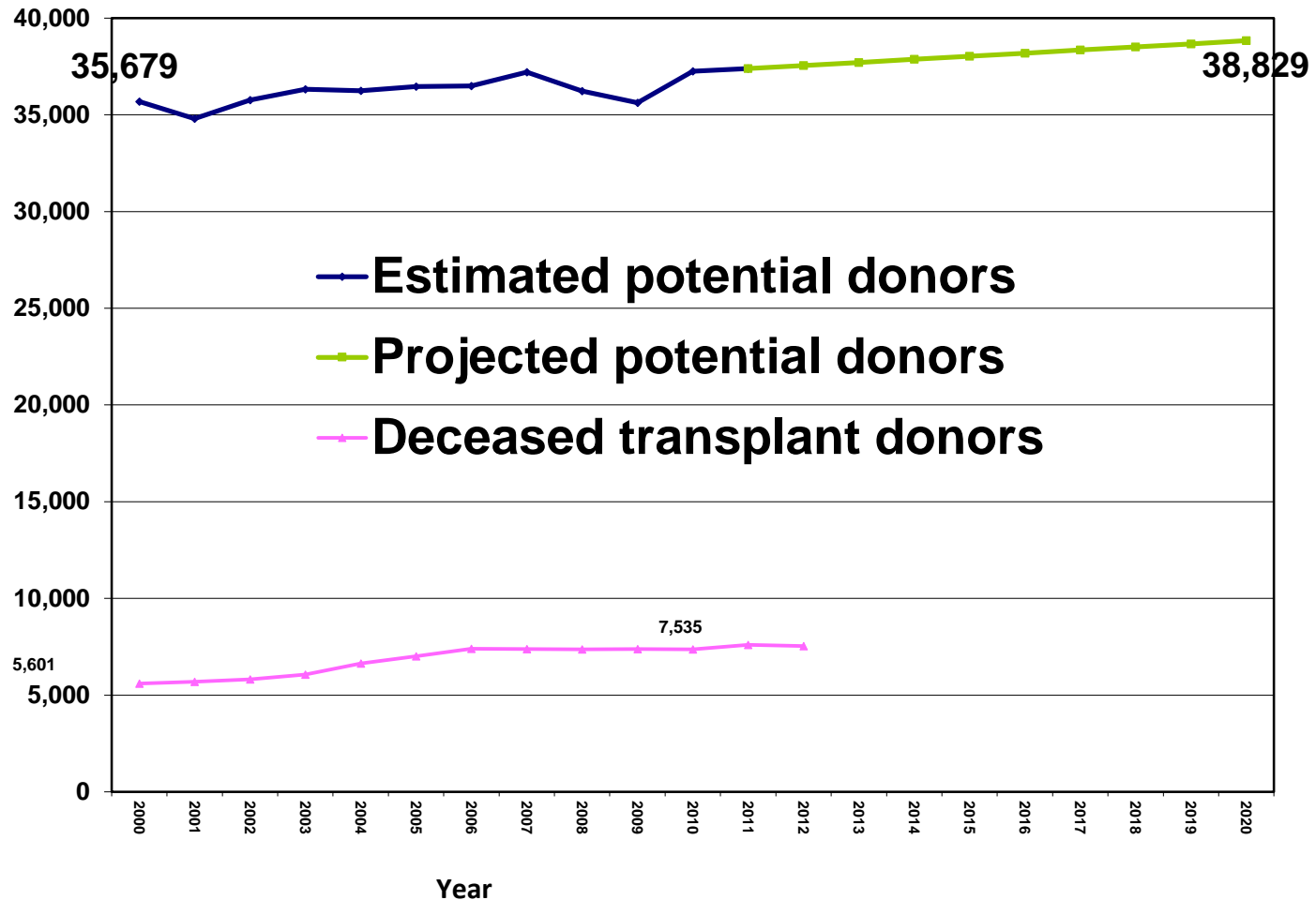
Projected donor potential to 2020

Deceased Donor Potential Projections 2011-2020
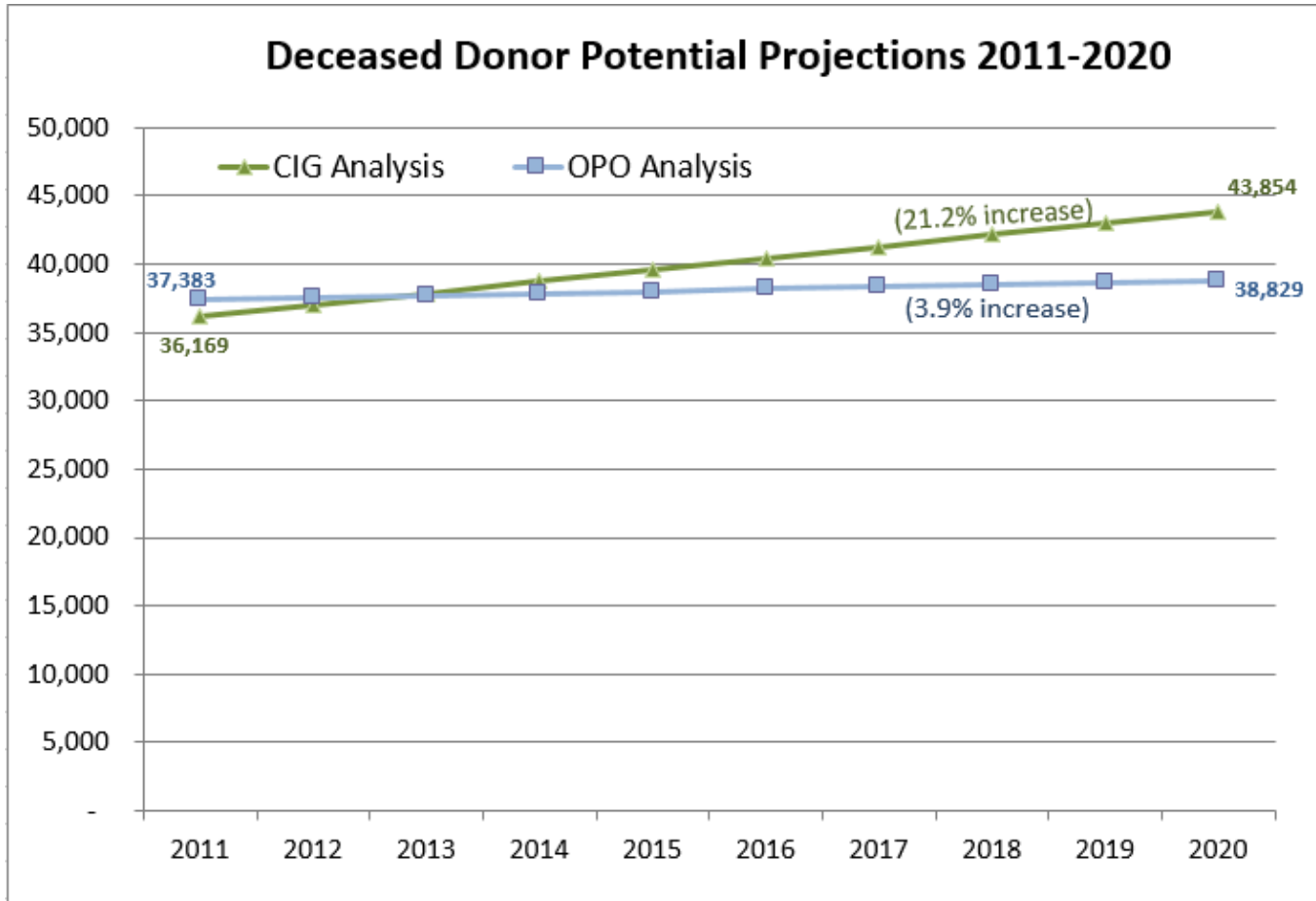
Interpretation caveats

- Two largely independent analyses closely converge suggesting significant donor potential exists.

- Some absolute contraindications from OPO survey could not be accounted for using variables within the NCHS data set. Likely results in a degree of over estimation that cannot be quantified.

- There is the assumption that the general patterns of change seen from 2000-2010 will continue.

- Changing demographics may affect projections

- Changing technology in donor management and organ treatments may change the assumptions used for projections

- Imminent donors already documented by OPOs approximately double the currently identified donor pool.

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Deceased Organ Donor Potential in Canada

- Study released December 2014

- Methodologically similar to US DDPS

- Data: Canadian Organ Replacement Registry (similar to OPTN)

- Data: Hospital Morbidity Database; contains clinical and administrative data on all Canadian hospitals

- Methods: similar filtering criteria

- Findings: Potential 3088, actual 520 (5.9:1), potential highest in older potential donor population. (US DDPS 5:1)

- Estimates based on full medical chart review in 3 jurisdictions were 26-54% lower than the study estimates.

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Review of major DDPS findings

- Significant donor potential exists: DDPS estimate 37,000 donors per year likely over estimates actual potential donors

- Majority of unrealized donor potential resides in an older donor population (>70% in 50 year old population)

- Projects minimal growth of donor potential through 2020: 1% per year

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System practice goals and policy changes suggested by DDPS

- Set specific, attainable, evidence based, performance goals

- Revise OPO performance metrics to remove disincentives to procurement of less than ideal donors, identify best practices, explore geographic variation

- Effect policy change and education to increase timely and complete donor hospital referrals

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System practice goals and policy changes suggested by DDPS

- Revise transplant center performance metrics and educate centers to reduce risk aversive behavior

- Multiple interventions to maximize results.

- Stakeholders include OPOs, OPTN, Tx programs, HRSA, CMS, third party payers, and patients

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Questions and Discussion?