Future of Policies to Increase Deceased Donations – Opt Out and Reciprocity Based Strategies

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Disclosures

Objectives:
Review, Analyze and Consider

- Primary reasons given in support of opt-out
- International data of opt-in versus opt-out performance
- Cultural and legal compatibility of donation defaults
- Ethical and legal components of reciprocity as a strategy
Opt-Out Policies

The legal authority to recover organs from deceased individuals unless a refusal to donate was registered.
Rationale for Opt-Out Policies

• Increase organ donation

• Bridge the gap between intent and action

• Signaling effect
International Deceased Organ Donation Opt-In vs Opt-Out Comparison
Ranked by Donors per Ten Thousand Deaths 2018

Mean Donation Rate is
27% higher in Opt In vs. Opt Out Jurisdictions - 2018

In 2018, the US overall organ donation rate was 38.1 donors per 10,000 deaths, second among reporting countries only to Spain (which has an opt-out donation policy). Six individual US states had rates that were higher than Spain, and US states comprised 43 of the top 50 jurisdictions. Furthermore, in the opt-in jurisdictions, the mean donation rate was 27% higher than rates in opt-out jurisdictions (32.6 vs 25.6 donors per 10,000 deaths, respectively). The data
Top 20 International Organ Donation Performance of Developed Donation Jurisdictions Ranked by Donors per Ten Thousand Deaths & Identifying Underlying Opt-In vs Opt-Out Laws

2018

Jurisdiction

Donors Per 10 Thousand Deaths

Why does Opt-In Work so well for the U.S.?

Uniform Anatomical Gift Act

• Based on gift law not informed consent
• Facilitates simple opt-in process
Donor Registration in the United States

over 168,000,000
as of YE 2019
Bridging the Gap Between Intent and Action

U.S. Opt-In Laws

- Provides two opportunities to get to a “yes”
  - First person
  - Surrogate
UAGA: Opt-in System Design
2 paths to a yes

Donor Authorization → No decision
Donor Authorization ← No decision

Surrogate Authorization → Surrogate Decline
Surrogate Authorization ← Surrogate Decline
Opt-out System Design
2 paths to a no

- Presumed consent
- Registered Refusal
- Surrogate Refusal
Bereaved relatives' decision about deceased organ donation: An integrated psycho-social study conducted in Spain

Social Science & Medicine
Volume 205, May 2018, Pages 37-47

Jorge S.Lópezab, José M.Martínezb, María Soria-Oliverc, Begoña Aramayona, Rubén García-Sánchez, María J. Martín, Carmen Almendrosb

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# Signaling Effect: Legal Models

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<th>SYSTEM DESIGN</th>
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<th>AUTHORIZE</th>
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<td>OPT-OUT</td>
<td>Based on social duties</td>
<td>Social compact or utilitarian</td>
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<td>OPT-IN</td>
<td>Based on individual rights</td>
<td>Autonomy</td>
<td>Authorized explicitly by patient or family</td>
<td>Recovery of organs</td>
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Signaling Effect: Cultural Match

• Individual autonomy principles

• Constitutional and other legal rights

• Creation of “no” registries
Evaluating Legal Models

• Designing a new legal system

• Changing laws in an existing system
  – Potential for rates to go down
  – Cultural or legal controversy
Over Half Support Presumed Consent

![Bar chart showing percent responses over time for Q17 Support Presumed Consent and Q17C Would Opt Out.](chart.png)

- Q17 Support Presumed Consent:
  - 2005: 41.9%
  - 2012: 51.1%
  - 2019: 56.3%

- Q17C Would Opt Out:
  - 2005: 29.7%
  - 2012: 23.4%
  - 2019: 34.4%
Methods
Retrospective review of donor registries from Corporació del Trasplante and Coordinación Nacional de Trasplante between January 2000 and December 2011 revealed donation rates (donors per million population [pmp]), family refusal, and number/percentage of non-donors.

Results
Organ donation rates decreased after passage of the new law from 6.5 (n = 111) in 2009 to 5.4 in 2010 (n = 92) and 6.5 donors pmp in 2011 (n = 113). Mean donation rate from 2000 to 2009 (before presumed consent) was 8.31 and from 2010 to 2011 (after presumed consent) 5.95 donors pmp; which represents a 29% decrease. Family refusal fluctuated between 32% and 41% between 2000 and 2009, but increased to an all time high of 50.4% in 2011. Finally as of December 2011, 2,520, citizens appeared to be nondonors in the Registry, which roughly represents 37% of those renewing their identification card (IC) or driving license (DI).

Conclusion
In Chile, presumed consent legislation not only did not increase but seems to have had a deleterious effect on organ donation, reflecting an increase in family refusals and a high percentage of nondonors in the registry.
Maximizing Opt-In

- Donor registry system design
  - Yes, carry-over
- Utilizing donor registration
  - BD and DCD
- Surrogate permission
  - OPO and Hospital collaborative approach
  - Timing
Beyond Opt-In and Opt-Out: Reciprocity

• Allocation priority tied to consent
  – Israeli model

• Incentive
  – Non-monetary benefit consistent with gift law

• Supported by equity and utility principles
• NOTA would need to be amended