OPT-OUT ORGAN DONATION
A PRO-CON DEBATE

Kristine E.W. Breyer, MD
Anne L. Donovan, MD

Outline
• Background
• Pro: We should change to an opt-out system
• Con: We should not change to an opt-out system

Organ donation in the US
• Opt-in system
• Governed by state and federal laws
  – National Organ Transplant Act (Public Law 98-507)
  – California Uniform Anatomical Gift Act (Cal Code 7150)
• Individual may indicate wish to donate through:
  – Record in donor registry database (Donate Life California website)
  – Driver’s license
  – Legal will
  – Any form of communication during a terminal illness, witnessed by 2 adults
  – Donor card or another symbol signed by the donor
• Another person may not make, amend, or revoke an anatomical gift without express contrary indication by the donor

http://codes.lp.findlaw.com/cacode/HSC/1/d7/1/3.5/s7150
http://www.organdonor.gov/becomingdonor/index.html
What is opt-out organ donation?

- Consent for donation is assumed unless a person explicitly opts out
- Also called “presumed consent” or “deemed consent”
- Used in multiple countries in Europe and worldwide

PRO: WE SHOULD CHANGE TO AN OPT-OUT SYSTEM

PRO-CON DEBATE

OPT-OUT ORGAN DONATION:

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No Disclosures
United States transplant statistics

<table>
<thead>
<tr>
<th>Organ</th>
<th>Number on Wait List</th>
<th>Median Waiting Time (days)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>135,691</td>
<td>63 – 2030</td>
</tr>
<tr>
<td>Kidney</td>
<td>109,613</td>
<td>597 – 2030</td>
</tr>
<tr>
<td>Liver</td>
<td>15,829</td>
<td>76 – 1314</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1,092</td>
<td>229 – 707</td>
</tr>
<tr>
<td>Kidney/Pancreas</td>
<td>2,080</td>
<td>263 – 758</td>
</tr>
<tr>
<td>Heart</td>
<td>4,138</td>
<td>63 – 423</td>
</tr>
<tr>
<td>Lung</td>
<td>1,648</td>
<td>429 – 966</td>
</tr>
<tr>
<td>Heart/Lung</td>
<td>38</td>
<td>386 – 2457</td>
</tr>
<tr>
<td>Intestine</td>
<td>253</td>
<td>149 – 286</td>
</tr>
</tbody>
</table>

*Wait time varies by blood type
**As of 4/11/15

www.optn.transplant.hrsa.gov

Only 40% of eligible donors in the US donate
(Family refusal rate: 50%)

1 organ donor can save up to 8 lives

www.organdonor.gov

How to enlarge donor pool?

• Living donors
• Mandatory choice
• Donation after cardiac death
• Change the definition of death — i.e. persistent vegetative state
• Accept higher risk donors
• Increase public awareness of “opting in”
• Change to an opt-out system

www.organdonationrates.org
Why change to opt-out?

- Increases number of donors
- Increases public willingness to donate
An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study

Lee Shepherd^{1,2}, Ronan E O’Carroll^{2} and Emmorn Ferguson^{2}

BMC Med Inform Decis Mak 2014, 14:131

<table>
<thead>
<tr>
<th></th>
<th>Opt-In Consent (per M)</th>
<th>Opt-Out Consent (per M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deceased Donors</td>
<td>9.98</td>
<td>14.24</td>
</tr>
<tr>
<td>Living Donors</td>
<td>9.36</td>
<td>3.49</td>
</tr>
<tr>
<td>Total Kidneys transplanted</td>
<td>22.43</td>
<td>28.32</td>
</tr>
<tr>
<td>Total livers transplanted</td>
<td>7.53</td>
<td>11.60</td>
</tr>
</tbody>
</table>

Opt-out systems increase willingness to donate

<table>
<thead>
<tr>
<th></th>
<th>Willing to Donate Own Organs (%)</th>
<th>Willing to Donate Family Member’s Organs (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent (Opt-in)</td>
<td>57%</td>
<td>44%</td>
</tr>
<tr>
<td>Presumed Consent (Soft opt-out)</td>
<td>64%</td>
<td>51%</td>
</tr>
<tr>
<td>Enforced Presumed Consent (Hard opt-out)</td>
<td>60%</td>
<td>51%</td>
</tr>
</tbody>
</table>

Why might opt-out increase numbers?

- Change in societal expectations and norms
- NOT donating in an opt-out system may be looked down upon
- Taking decision-making away from grieving family members
- Changes to the system
- Overcoming inertia of “opting in”
Hand hygiene is a key health issue, says CMO

Michael Day LONDON
Liam Donaldson, the chief medical officer for England, has named, in his latest annual report, “unacceptably poor” hand hygiene in hospitals and the chronic lack of organs for transplantation as the two most pressing public health issues.

BMA calls for opt-out system

Soft opt-out organ donation
The BMA is calling for:
• Increased public campaigning to promote organ donation
• A soft opt-out system for organ donation
BMA has long advocated a “soft” opt-out system with safeguards for organ donation and continues to believe this is the best option for the UK to reduce the shortage of organs.

Types of opt-out systems

• Enforced presumed consent (“hard opt-out”) – Organ donation is automatic for those who have not opted out if organs are in good condition
• Unenforced presumed consent (“soft opt-out”) – Input from families is allowed
• In practice, most families are approached in opt-out systems
Wales implements opt-out system

230 days until the way you become an organ donor will change in Wales.
From the 1 December 2015, the way we choose to become organ donors will change. Now is the time for us to understand what this means and talk about it with our loved ones.

Is opt-out organ donation ethical?

- Consent can be explicit or implicit
- Patient and family retain rights
- Continue to respect patient autonomy
- Benefit of many over benefit of one

Summary

- Organ shortage is a major public health problem
- Other methods to increase donor pool limited
- Opt-out systems have higher donors per capita
- Implicit (presumed) consent is ethical
- Opt-out organ transplant system may be a good option for increasing organ availability
References


CON: WE SHOULD NOT CHANGE TO AN OPT-OUT SYSTEM

1 ORGAN DONOR CAN SAVE 8 LIVES.

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No Disclosures

Outline: Keep ‘Opt-In’

- Ethical and Legal Principles
  - Precedents
  - Disparities
- Data on Opt-out outcomes

Opt-out Violates Autonomy

- Presumed Consent violates the ethical principle of patient Autonomy

- Operating under Presumption

Lack of Informed Consent
Autonomy

- “Personal rule of the self that is free from both controlling interferences by others and from personal limitations that prevent meaningful choice”
- Cornerstone of modern era medical ethics
- Informed Consent
- Patient-centered healthcare

Autonomy Precedent

- Jehovah’s Witness:
  - Legal right to refuse life saving therapy based upon religious or personal values
  - Requires informed consent
  - Precedent set in 1914 *Schloendorff v. New York Hospital*

Autonomy Precedent

- Human Research
  - Nuremberg Code of Ethics
  - Department of Health & Human Services
  - Food and Drug Administration
  - Institutional review boards

Autonomy Precedent

- Fetal Stem Cells
  - Informed consent is required
- Umbilical Cord Blood
  - Informed consent is required
Disparities

• Where are our current gaps?

- Lack of universal access to healthcare
- Organs procured from general population may not benefit the general population

Disparities

CONSENT RATES BY ETHNICITY

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Range of consent rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whites*</td>
<td>[0.5, 0.7]</td>
</tr>
<tr>
<td>Hispanics*</td>
<td>[0.4, 0.6]</td>
</tr>
<tr>
<td>Blacks*</td>
<td>[0.3, 0.5]</td>
</tr>
<tr>
<td>Asians**</td>
<td>[0.2, 0.4]</td>
</tr>
</tbody>
</table>

*P<0.001, **P<0.003 comparing consent rates across regions.

Disparities

ANNUAL TRANSPLANTATION RATE

Disparities

COUNTY POVERTY LEVEL & RATE OF TRANSPLANTATION
Is Presumed Consent Worth it?

- Organ shortage
- Does presumed consent help to fulfill this gap?

Chile

Donation Rates

Spain

1979: Legislation for Presumed Consent
- Donor rate ~ 14 per million population
1979: Legislation for Presumed Consent
– Donor rate ~ 14 per million population

1989:
– Donor rate ~ 14 per million population

• RATE DONATION WAS UNCHANGED

Is the United States Ready for Presumed Consent?
Failed Legislation:
• Pennsylvania
• Maryland
• Delaware
• Texas
• New York
California Donor Network
• Official Position: against
Opt-in!

- Presumed consent violates Autonomy
- Does not address disparities
- Has not been supported in the United States
- Does not work