Using Research to Drive Policy

Dorry Segev, MD, PhD
Vice Chair for Research, JHU Surgery
The HOPE Act

• Encouraging outcomes with HIV-to-HIV in South Africa

• Encouraging outcomes with NIH HIV trial (HIV negative organs into HIV+ patients)
42 U.S.C. 274(b) Section 372(b)

"...including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome"

(National Organ Transplant Act, 1984/88)
Motivation

- There are >100,000 people on the list
- Many die before their first organ offer
- We likely throw away many organs because they come from a donor who is HIV+ (and it would be illegal to use them)
- Hypothesis: Someone on the waiting list is likely to benefit from an HIV-infected organ
International experience: South Africa

- 14 patients: HIV-HIV transplantation
  - HAART on day 1 or 2
  - ATG + MMF/Tac/Pred
  - Up to 4 years post-tx: Undetectable viral loads & stable renal function

Muller et al., NEJM, 2010

- State representative Larry McKeon
- NOTA trumps state law
Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States


*a Department of Surgery, Johns Hopkins School of Medicine, Baltimore, MD
b Department of Surgery, Georgetown University School of Medicine, Washington, DC
c Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD
d Department of Epidemiology, Johns Hopkins School of Public Health, Baltimore, MD
e HIV Research Network, Baltimore, MD
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How many donors are we talking about?
How many lives would be saved?
How much money would Medicare save?

Received 03 December 2010, revised 24 January 2011 and accepted for publication 09 February 2011
Estimating Donors: NIS

• Nationwide Inpatient Sample
  20% stratified cluster sample of acute-care hospitals in the United States
• Can ascertain in-hospital deaths + ICD9 dx
• Included HIV
• Excluded by age, ifxn, malignancy, other contraindications to donation (liver vs kidney)
• Scale based on sample design

(Boyarsky/Segev, AJT, 2011)
Estimating Donors: NIS

- 8600 (7992–9109) HIV inpatient deaths/yr
- 534 (481-652) potential HIV donors (most excluded for infection)
- Approximately:
  - 63 kidney-only
  - 221 liver-only
  - 250 kidney+liver

(Boyarsky/Segev, AJT, 2011)
Estimating Donors: HIVRN

• HIV Research Network
  Consortium of 18 sites across US, longitudinal clinical information system of HIV+ patients
• Detailed clinical information + death
• Excluded by age, ADI within 1yr, CD4<200, detectable plasma HIV-1 RNA >400 copies/mL, comorbidities, multi-organ failure
• Scale based on CDC estimates of HIV+ deaths

(Boyarsky/Segev, AJT, 2011)
Estimating Donors: HIVRN

• 3798 deaths in HIVRN during study period
• 1/4 excluded because of no recent CD4/RNA
  1/4 excluded with ADI within 1 yr
  1/3 excluded for CD4<200 or RNA>400
  29% died of trauma/ICH/CVA/etc
• Remaining scaled up to 494 (441-533)
  potential donors; 93% had HAART regimen on
  record in HIVRN database

(Boyarsky/Segev, AJT, 2011)
A Push to Let H.I.V. Patients Accept Organs That Are Infected

By PAM BELLUCK

David Aldridge of Los Angeles had a kidney transplant in 2006, but he will soon need another. Like many people living with H.I.V., he suffers from kidney damage, either from the virus or from the life-saving medications that keep it at bay.

Until recently, such patients did not receive transplants at all because doctors worried that their health was too compromised. Now they can get transplants, but organ-donor waiting lists are long. And for Mr. Aldridge, 45, and other H.I.V. patients, a potential source of kidneys and livers is off limits, because it is illegal to transplant organs from donors who test positive for H.I.V.

Other experts are calling for repeal of the provision that bans such transplants, a 23-year-old amendment to the National Organ Transplant Act.

“The clock is ticking more quickly for those who are H.I.V.-positive,” said Dr. Dorry Segev, transplant surgery director of clinical research at Johns Hopkins and a co-author of a new study indicating that 500 to 600 H.I.V.-infected livers and kidneys would become available each year if the law were changed.

“We have a huge organ shortage. Every H.I.V.-infected one we use is a new organ that takes one more person off the list.”

The ban on transplanting or
HIV-INFECTED ORGANS CAN SAVE LIVES, DOCTORS SAY
S330/HR698: Progress

- Drafted around March 2012
  Boxer/Capps legislative assistants
Increasing Organ Donation
Repeal of the 1980s federal ban on transplanting organs from
HIV+ donors to benefit HIV+ recipients

HIV Medicine Association • amfAR, The Foundation for AIDS Research
Human Rights Campaign • AIDS United • Treatment Action Group

Invite you to a Congressional Briefing held in collaboration with the offices of

Senator Barbara Boxer
Senator Tom Coburn, MD
Congresswoman Lois Capps, RN

Wednesday, June 27, 2012
12:00 - 1:00 pm
Room SVC 201-00
* Lunch will be provided *

Featuring

Dorry Segev, MD, PhD
Director, Clinical Transplant Research
Associate Professor of Surgery & Epidemiology
Johns Hopkins School of Medicine

Peter Stock, MD, PhD
Principal Investigator, NIH HIV+ Solid Organ Transplant Study
Professor of Surgery
University of California, San Francisco School of Medicine

Richard Moore, MD, MHS
Board of Directors, HIV Medicine Association
Director, Moore Clinic for HIV Care
Professor of Medicine
Johns Hopkins School of Medicine

Joel Newman
Assistant Director, Communications
United Network for Organ Sharing (UNOS)

Thomas Lane
Kidney Transplant Recipient

Kindly RSVP by June 25 to bjb@jhmi.edu
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S330/HR698: Progress

• Drafted around March 2012
  Boxer/Capps staff
• HHS Technical “Assistance” June 2012
• Revision through end of 2012
• CBO score process started
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S330/HR698: Progress

• Introduced Feb 14, 2013

• Senate:
  – HELP Committee: 3/20/13
  – Floor Vote: Unanimous 6/17/13

• House:
  – E&C Committee: 7/17/13
  – Suspension: 11/12/13

• Obama: 11/21/13
The Norwood Act

• > 100,000 patients on the kidney waiting list
• Many are sensitized, very long waiting times
• Many patients every year have a willing, healthy donor but are relegated to waiting list because of incompatibility
• Hypothesis: Exchanging kidneys would help them get transplanted
Kidney Exchange: Paradigm

Donor A

Recipient O

*ABO Incompatible*

Donor O

Recipient A

*Positive Crossmatch*
42 U.S.C. 274(e)

"It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation..."

(National Organ Transplant Act, 1984/88)
Kidney Paired Donation and Optimizing the Use of Live Donor Organs

Dorry L. Segev, MD
Sommer E. Gentry, MS
Daniel S. Warren, PhD
Brigitte Reeb, MFA
Robert A. Montgomery, MD, DPhil

• How many pairs?
• How best to match them?
• How many lives would be saved?
• How much money would Medicare save?
Each Patient has between 1-4 available donors

(Segev, JAMA, 2005)
Mathematical Modeling: Monte Carlo Simulation

Each Patient has 1-4 Potential Donors

Medical and Psychosocial Workup

Eligible

ABO & XM test

Donor

Patient

Failed

Check other donors for eligibility

Compatible

Incompatible

Direct Donation

Keep simulating patients until live directed donors are found

Check other donors for compatibility
If none are compatible: Join KPD

(Segev, JAMA, 2005)
Kidney Exchange: Optimization

• Field of applied mathematics used in airline scheduling, online driving directions, ...

• “the most influential academic discipline you’ve never heard of” (Boston Globe)

• Optimization technology helps utilize scarce resources by quickly and efficiently considering ALL solutions to a given problem and picking the best
Kidney Exchange: IP Optimization

Pair 3
Donor: B
Recipient: A

Pair 4
Donor: A
Recipient: O

Pair 1
Donor: A
Recipient: O
XM+

Pair 2
Donor: O
Recipient: A

200 x2

275 x3

335 x1

x1 = pair 1 and 2 match
x2 = pair 1 and 3 match
x3 = pair 2 and 4 match

objective:
max(335*x1+200*x2+275*x3)

subject to constraints:
x1,x2,x3 ∈ \{0,1\}
x1+x2≤1
x1+x3≤1

(Segev, JAMA, 2005)
Assessing Potential Impact

• The potential impact of KPD on living kidney donation in the US is profound
• 1500-3000 patients every year are relegated to the deceased donor waiting list who have a living, healthy, but incompatible donor
• 50-75% of these patients should match in KPD at a national level

Segev, JAMA 2005; Segev, AJT 2005; Gentry, AJT 2005
The Kidney Connection

DORRY SEGEV & SOMMER GENTRY

The couple tweaked a decades-old algorithm to develop a better way to match kidney donors and patients. Their optimized matching system could save hundreds of lives each year.
THE BIG IDEA

Dorry Segev (left) and Sommer Gentry

The Right Match

At any time, 60,000 people in the United States need a kidney transplant. Relatives usually make the best donors but, for a variety of reasons, aren't always compatible. In such cases, patients can wait years for a cadaver kidney, and some end up dying before a healthy organ arrives.

Hoping to shorten those waiting times, Johns
A BILL

To amend the National Organ Transplant Act to clarify that kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.

1 Be it enacted by the Senate and House of Representa-

2 tives of the United States of America in Congress assembled,

3 SECTION 1. SHORT TITLE.

4 This Act may be cited as the “Living Kidney Organ

5 Donation Clarification Act of 2007”.

2 SEC. 2. AMENDMENT TO THE NATIONAL ORGAN TRANSPLANT ACT.

3 Section 301(a) of the National Organ Transplant Act (42 U.S.C. 274e(a)) is amended by adding at the end the following: “For purposes of this section, kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.”.
Title: A bill to amend the National Organ Transplant Act to clarify that kidney paired donations shall not be considered to involve the transfer of a human organ for valuable consideration.

Sponsor: Sen Levin, Carl [MI] (introduced 2/1/2007)    Cosponsors (10)  

Related Bills: H.R.710


COSPONSORS (10), BY DATE [order is left to right]:  (Sort: alphabetical order)

H.R.710
Title: To amend the National Organ Transplant Act to clarify that kidney paired donation does not involve the transfer of a human organ for valuable consideration.
Cosponsors (29)
Related Bills: S.487

COSPONSORS (29), ALPHABETICAL [followed by Cosponsors withdrawn]: (Sort: by date)

DSAs (donation service areas)
Range of transplant rates, by DSA

MELD 38-39: 18% to 86%
MELD 38-39: 14% to 82%
“Neither place of residence nor place of listing shall be a major determinant of access to a transplant.”
December 29, 1999
Iowa Turf War Over Transplants Mirrors Feuds Across the Nation

“But the debate is not just about saving lives... the fight, they say, is about which transplant centers -- not which patients -- will get the scarce organs, and the profits and prestige that go with them.”
The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas - each serving a population base of at least 9 million people.”

Institute of Medicine, 1999.
The committee recommends that the DHHS Final Rule be implemented by the establishment of Organ Allocation Areas - each serving a population base of at least 9 million people.”

Institute of Medicine, 1999.

Doesn't it matter which 9 million people?
Optimal Redistricting

• Redistricting uses integer programming to design geographic boundaries between units
  – There is a substantial body of OR literature on redistricting for voting districts and school districts, dating from 1950s to the present

• We partition the DSAs into new districts
  – design first (OPL/CPLEX), then analyze (Simulation)
Redistricting Objective

• Minimize *total disparity*
  – Disparity = difference between number of donors a district *should* have (if organs went to highest MELD patient anywhere in the country) and number of donors in a proposed district
  – Minimize sum of these disparities over all districts

• Pure equity objective
  – MELD predicts waiting list death
  – Getting each liver to the sickest candidate should also be efficient, reducing waiting list deaths
Liver Committee’s design constraints

• Districts should be contiguous.*
• The number of districts should be at least 4 and no more than 8.
• The maximum allowable median volume-weighted travel time between DSAs placed in the same district should be 3 hours.
• Minimum number of transplant centers per district is 6.
Minimize \[ \sum_{i \in \text{REG}} \sum_{k \in \text{DSA}} \delta_{ik}^2 w_{ik} \]

Subject to:

\[ L_{\text{max}} \leq \text{FairVariation} \]
\[ \sum_{l \in \text{LEV}} x_{il} = 1 \quad \forall i \in \text{REG} \]
\[ \sum_{i \in \text{REG}} w_{ki} = 1 \quad \forall k \in \text{DSA} \]
\[ \sum_{k \in \text{DSA}} d_k w_{ki} = D_i \quad \forall i \in \text{REG} \]
\[ \sum_{k \in \text{DSA}} c_{ki} w_{ki} = C_l \quad \forall i \in \text{REG}, \forall l \in \text{LEV} \]
\[ \sum_{l \in \text{LEV}} x_{il} l = L_i \quad \forall i \in \text{REG} \]
\[ \sum_{l \geq m} C_{li} \geq D_i - M (1 - x_{im}) \quad \forall i \in \text{REG}, \forall m \in \text{LEV} \]
\[ \sum_{l \geq m} C_{li} \leq D_i + M x_{im} \quad \forall i \in \text{REG}, \forall m \in \text{LEV} \]

\[ \text{FairVariation} = \text{max allowed difference of MELD at transplant} \]

\( DSA = \) set of Donor Service Areas
\( \text{REG} = \{1,2,\ldots, 11\} \)
\( \text{LEV} = \) set of sickness levels
\( \{\text{MELD }<14, 15-19, 20-25, 26-30, 31-35, 36-38, 39, 40\} \)
\( \text{seed}_{ik} = 1 \) if DSA \( k \) is the seed for region \( i \), 0 else
\( \delta_{ki} = \) distance between center of region \( i \) and DSA \( k \)
\( d_k = \) donors in DSA \( k \)
\( c_{ki} = \) candidates in DSA \( k \) with MELD scores at level \( l \)
\( w_{ki} = 1 \) if DSA \( k \) is in the region \( i \)
\( C_l = \) candidates in region \( i \) with MELD scores at level \( l \)
\( x_{il} = 1 \) if region \( i \) transplants candidates at level \( >m \), 0 else
\( L_i = \)sickness level at which region \( i \) runs out of livers
\( L_{ij} = |L_i - L_j| \) for all \( i, j \) in \( \text{REG}, \quad L_{\text{max}} \geq L_{ij} \) for all \( i, j \) in \( \text{REG} \)

Gentry/Segev, AJT, 2013
Minimize: 

\[ \sum_{k \in \mathcal{K}} \left| \sum_{i \in \mathcal{I}} p_{ik} W_{ik} - \sum_{i \in \mathcal{I}} d_{ik} W_{ik} \right| \]

Objective: minimize geographic disparity in liver availability by minimizing the sum of misdirected livers
subject to: \( \sum_{k \in \mathcal{K}} W_{ik} = 1 \quad \text{for all } i \in \mathcal{I} \)
\[ W_{ik} - Y_k \leq 0 \quad \text{for all } i \in \mathcal{I} \text{ and } k \in \mathcal{K} \]

Each DSA is assigned to one district

If a DSA \( k \) is assigned as the center of the district containing DSA \( i \),
\[ Y_k \] should be 1
\[ \sum_{k \in \mathcal{K}} Y_k = N \]
\[ \sum_{i \in \mathcal{I}} h_i W_{ik} \geq \bar{h} Y_k \quad \text{for all } k \in \mathcal{K} \]

Number of districts is \( N \)

Require at least \( \bar{h} \) transplant centers in each district
$W_{ik} \tau_{ik} \leq \bar{T} \quad \text{for all } i \in \mathcal{I} \text{ and } k \in \mathcal{K}$

Maximum transport time from each district to its district center is $\bar{T}$
\[
\sum_{k \in K} \alpha_{ijk} W_{ik} \leq 1 - Y_j \quad \text{for all } i \in I \text{ and } j \in K
\]

\[\delta_{ij} = \text{volume-weighted distance from DSA } i \text{ to } j\]

\[\alpha_{ijk} = \begin{cases} 1 \text{ if } \delta_{ik} > \delta_{ij}, & 0 \text{ if not} \end{cases}\]

Every DSA is assigned to its nearest district center

(Daskin, Service Science, 2010)
Liver Simulated Allocation Model

Thompson and Waisanen, 2004

Diagram:
- Resampled patient arrivals
- Resampled organ arrivals
- District plan
- Waiting list + resampled MELD updates
- Liver allocation
- Accept or decline liver
- Post-transplant outcome model
- Post-transplant deaths
- Waiting list deaths and removals
- Relisting after transplant fails
- Offer declined
Disparity in transplant MELD, local
Disparity in transplant MELD, 8 districts
Redistricting is cost-saving

<table>
<thead>
<tr>
<th>Allocation</th>
<th>Transport Cost</th>
<th>Pre-transplant Cost</th>
<th>Transplant Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local</td>
<td>$125 mil</td>
<td>$1629 mil</td>
<td>$3576 mil</td>
<td>$5330 mil</td>
</tr>
<tr>
<td>Regional</td>
<td>$165 mil</td>
<td>$1487 mil</td>
<td>$3468 mil</td>
<td>$5120 mil</td>
</tr>
<tr>
<td>4 Districts</td>
<td>$191 mil</td>
<td>$1358 mil</td>
<td>$3453 mil</td>
<td>$5002 mil</td>
</tr>
<tr>
<td>8 Districts</td>
<td>$176 mil</td>
<td>$1387 mil</td>
<td>$3462 mil</td>
<td>$5025 mil</td>
</tr>
</tbody>
</table>
Receiving a life-saving liver transplant from a deceased donor seems to hinge on what part of the country the hopeful recipient of an organ resides, with odds weighing more heavily in favor of patients in less densely populated parts of the country. Organ transplantation policy researchers addressed this disparity from various perspectives during Sunday’s Controversies in Transplantation.

“The consensus among major organ policy experts is favoring small, incremental steps to broaden distribution with the goal to minimize waitlist deaths and limit the distance the organ needs to travel,” said James F. Markmann, MD, PhD, Chief, Division of Transplant Surgery, Massachusetts General Hospital, Boston. “Elimination of geographic disparities may not only...”
The existing geographic disparity in allocation of organs for transplant is \textbf{unacceptably high}.

The Board directs organ-specific committees to define the metric of fairness and any constraints for each organ system by June 30, 2013...

The Board requests that \textbf{optimized systems} utilizing overlapping versus non-overlapping geographic boundaries be compared, including using or disregarding current DSA and region boundaries in allocation.
1. Committee Priorities, 2013-2014. The Committee leadership met via conference call to prioritize the long list of approved projects for the 2013-2014 year. The top three priorities for the year are as follows:

- Liver Distribution Redesign Modeling
- Develop materials to educate RRB members / promote consistent review of exceptions / Ongoing review of MELD/PELD Exceptions
- Changes to Policy for Hepatocellular Carcinoma (HCC) Exceptions
September 2014 public forum
Learn the policy
Think from the trenches

Make media connections
Learn how to talk to media

Learn the science
Publish for the policymakers

Learn how congress works (Fellowship?)
Work with advocacy groups, societies, LAs
Epidemiology Research Group in Organ Transplantation (D Segev, Director)

Core Research Group

**Medicine/Surgery**
- Morgan Grams, MD, PhD
  Nephrology Faculty; PhD Graduate (K08)
- Elizabeth King, MD
  Surgery Resident; PhD Student (F32)
- Babak Orandi, MD MSc
  Surgery Resident; PhD Student (F32)
- Kyle Van Arendonk, MD PhD
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  Surgery Resident; MPH/MBA Student
- Rebecca Craig-Schapiro, MD
  Surgery Resident
- Trevor Ellison, MD
  Surgery Resident; PhD/MBA Student (KL2)
- Jackie Garonzik-Wang, MD PhD
  Surgery Resident; PhD Graduate (KL2)

**Epidemiology**
- Allan Massie, PhD
  Epidemiology (K01 pending)
- Mara McAdams, PhD
  Epidemiology (K01 pending)
- Abi Muzaale, MD, MHS
  Epidemiology Postdoc
- Megan Salter, PhD
  Epidemiology Postdoc (T32)
- Andrew Law, ScM
  Epidemiology Staff
- Xun Luo, MD MPH
  Epidemiology Staff
- Anna Poon, MHS MS
  Epidemiology Staff

**Computational Science**
- Sommer Gentry, PhD
  Computer Science (HRSA)
- Eric Chow, MHS
  Decision Process Models
- Corey Wickliffe, MHS
  Geographic Systems

**Research Assistants**

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- Amanda Brennan
- Erika Jones
- Kathryn Marks
- Komal Kumar

**Part-Time:** (JHU Work-Study)
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- Kate Appel
- David Batchelor
- Tiffanie Be
- Olivia Berman
- Jeremy Fama
- Kevin Fitzell
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- Ashley Millette
- Steven Park
- Brian Pomares
- Leland Pung
- Katrina Rios
- Bisola Salisu
- Chelsea Sicat
- Mia Spad
- Bridget Burke
- Ruth Namuyinga
- Josephine Pourdavoud
- Sunitha Suresh

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- Andrew Cameron, MD PhD
  Surgery: Collaborator
- Desai, Niraj MD
  Surgery: Collaborator
- Linda Kao, PhD
  Epidemiology: Coinvestigator
- Daniel Scharfstein, ScD
  Biostatistics: Coinvestigator
- Ravi Vardhan, PhD
  Biostatistics: Coinvestigator
- Lucy Meoni, ScM
  Biostatistics: Coinvestigator
- Nabil Dagher, MD
  Surgery: Mentee
- Andrew Singer, MD PhD
  Surgery: Mentee (K08 pending)
- Elliott Haut, MD
  Surgery: Mentee (KL2; PhD Student)
- Kim Steele, MD
  Surgery: Mentee (K23 pending)
- Diane Schwartz, MD
  Surgery: Mentee
- Aliaksei Pustavoitau, MD
  Anesthesiology: Mentee (R03 pending)

Natasha Gupta
Medical Student (Doris Duke Foundation)
Mohamud Qadi
Medical Student
Josie Maione
Medical Student (NIH MSTAR)
Lauren Kucirka, ScM
MD/PhD Student (F30)