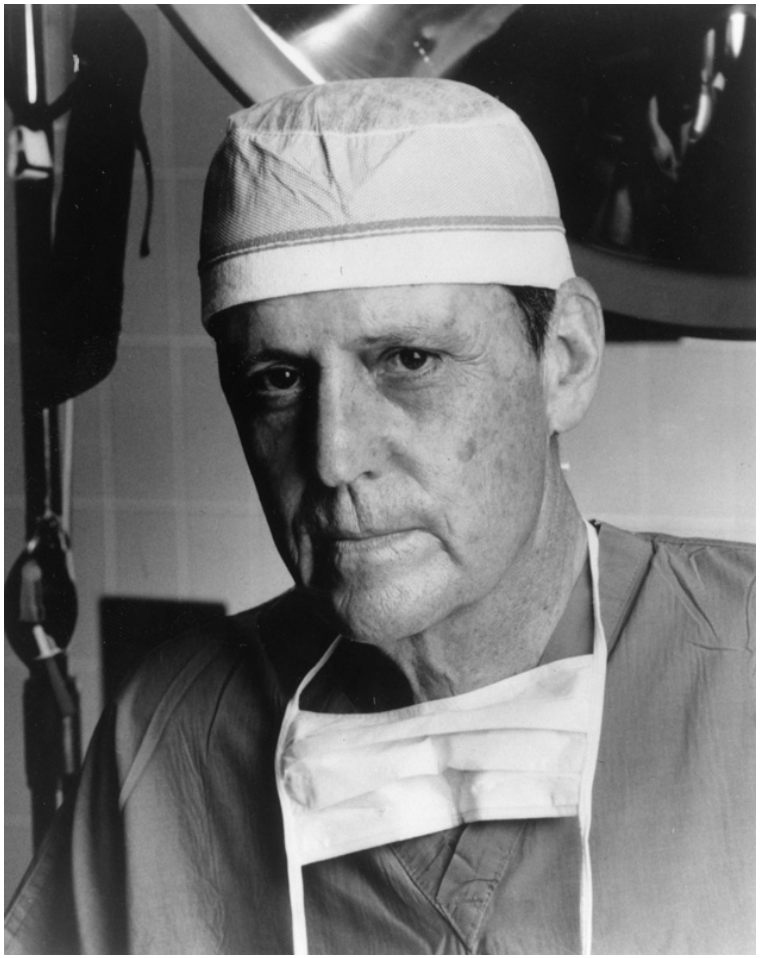
Transplantation: Complex problems, simple solutions.

Timothy L Pruett, MD

ASTS Presidential Address

No conflicts of interest, no off label discussions.

First ASTS presidential address, 1975 Thomas E. Starzl



- Birth of a healthy baby that was not anticipated by mother.
- ASTS' mission was to be promotion of transplant research and promulgation of information to the community. Avoid freezing IS treatment in current form.
- Cautionary tones re: relationship with government and insurers is fragile (do not overly focus on lobbying or payments), monitor training programs, establish and maintain professional standards

How the ASTS has grown: 2016/2017 has been a fascinating year

- Disseminate information: ATC, Winter symposium, AJT
- Training
  - TACC, taking on task of credentialing fellows, legal structure.
  - LDP: ASTS/Kellogg School of Management effort.
- Research
  - IOM (deceased donor research), Arnold Foundation grants (payment live donor lost wages, metrics), ASTS foundation funding for member research
- Advocacy/Regulation
  - Public metrics and how presented (5 tier), OPTN and SRTR MACRA is active, CMS innovation projects, WS/Kellogg session on conflict resolution
- Optimal patient care
  - TTC (new meds for transplant patients)
  - NLDAC
- Organ availability: a major need in the US (and globally).
  - Subject of last two winter symposiums
  - Decreasing organ “discards” from DD: subject of upcoming NKF conference and theme of several OPTN papers.
  - Live donor task force, lost wages, NLDAC
  - Lack of liver availability led to conflict resolution session at WS

Organ donation 2.0: turning ideas into action

- Too many waiting, not enough organs
  - About 120,000 waiting for an organ transplant
  - >2.5M deaths every year vs <10,000 Deceased Donors
  - 33,610 transplants vs. 58,855 WL additions in 2016
  - 13,189 people died/removed as too sick to txp in 2016
- Insufficient organ supply is a problem.
  - Increasing the numbers of deceased donor organs
    - Using organs from donors with variable potential (DCD), need more from the existing pool of DD.
  - Living donation: Static numbers in the country
    - Continued statements about incentivize vs. altruism to increase live organ donation.
  - With limited numbers of organs: who receives and who doesn't becomes increasingly important.

Our current society is polarized over just about everything

- Issues are simplified, summarized in 140 Twitter characters.
- Reacting to situations has become normative.
- Listening to each other is becoming the exception.
- Differing perspectives are discounted before discussed.
- US culture is contentious, typically demonizing opinions contrary to our own.

Transplantation issues are complex and we often need to deal with conflicting perspectives: can't talk about one without other

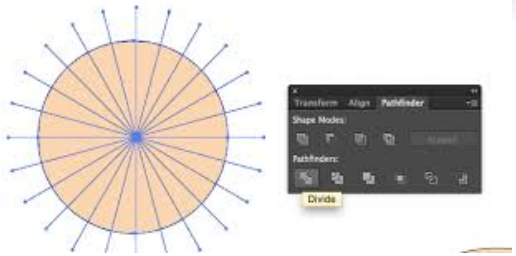
- Benefit/risk
  - Live donation
  - Transmitted disease (PHS guidelines)
- Abundance/scarcity
  - Increase use of deceased donor organs/outcomes
  - Reconfiguring allocation models (re-Districting)
- Life/death
  - Urgency to increase organ availability/misuse of people to meet unmet demand.

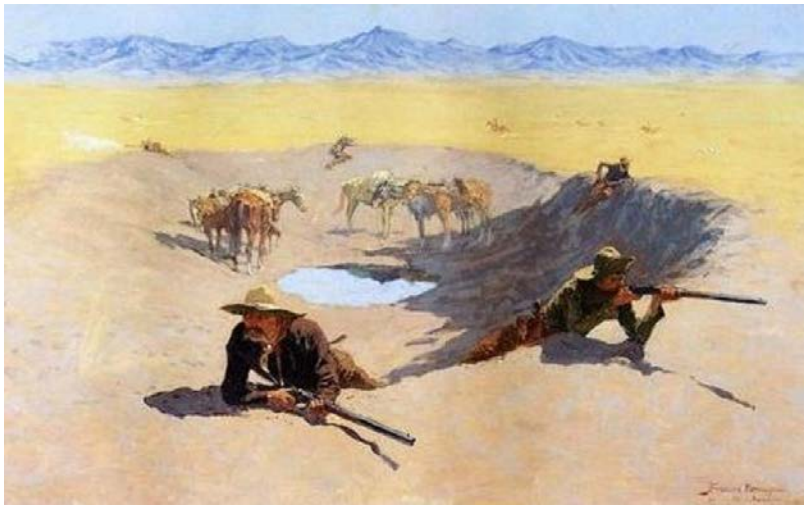
For every complex problem there is an answer that is clear, simple, and wrong.

H. L. Mencken

What happens when there isn’t enough?

Not enough (organs) for everyone: the consequences affect the response





The problem with not enough organs? Everyone's getting sicker, but not equally so.

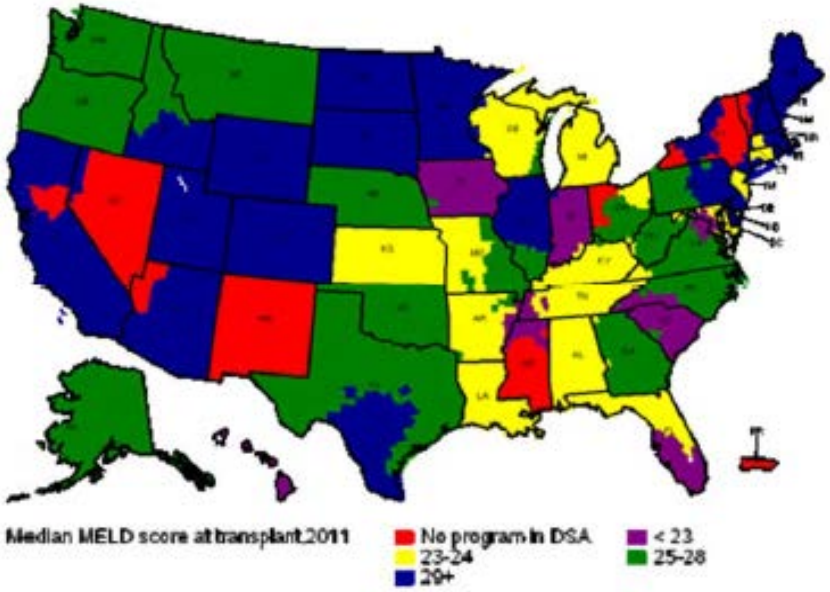
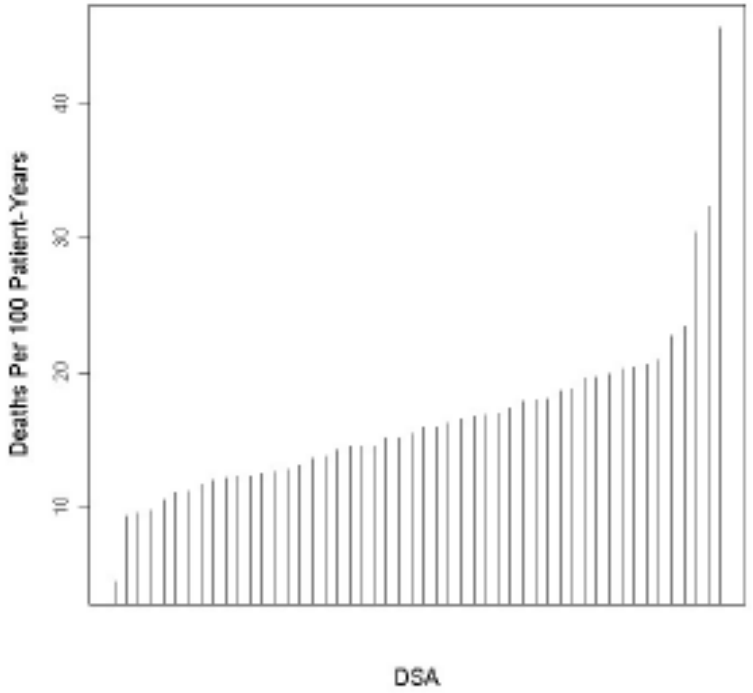


Figure 3: Median MELD score at Transplant, 2011

Pt deaths/100 pt-yrs on WL by DSA, 2011



Redesigning liver distribution to reduce variation in access to liver transplantation
https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf

US Liver availability: heterogeneous

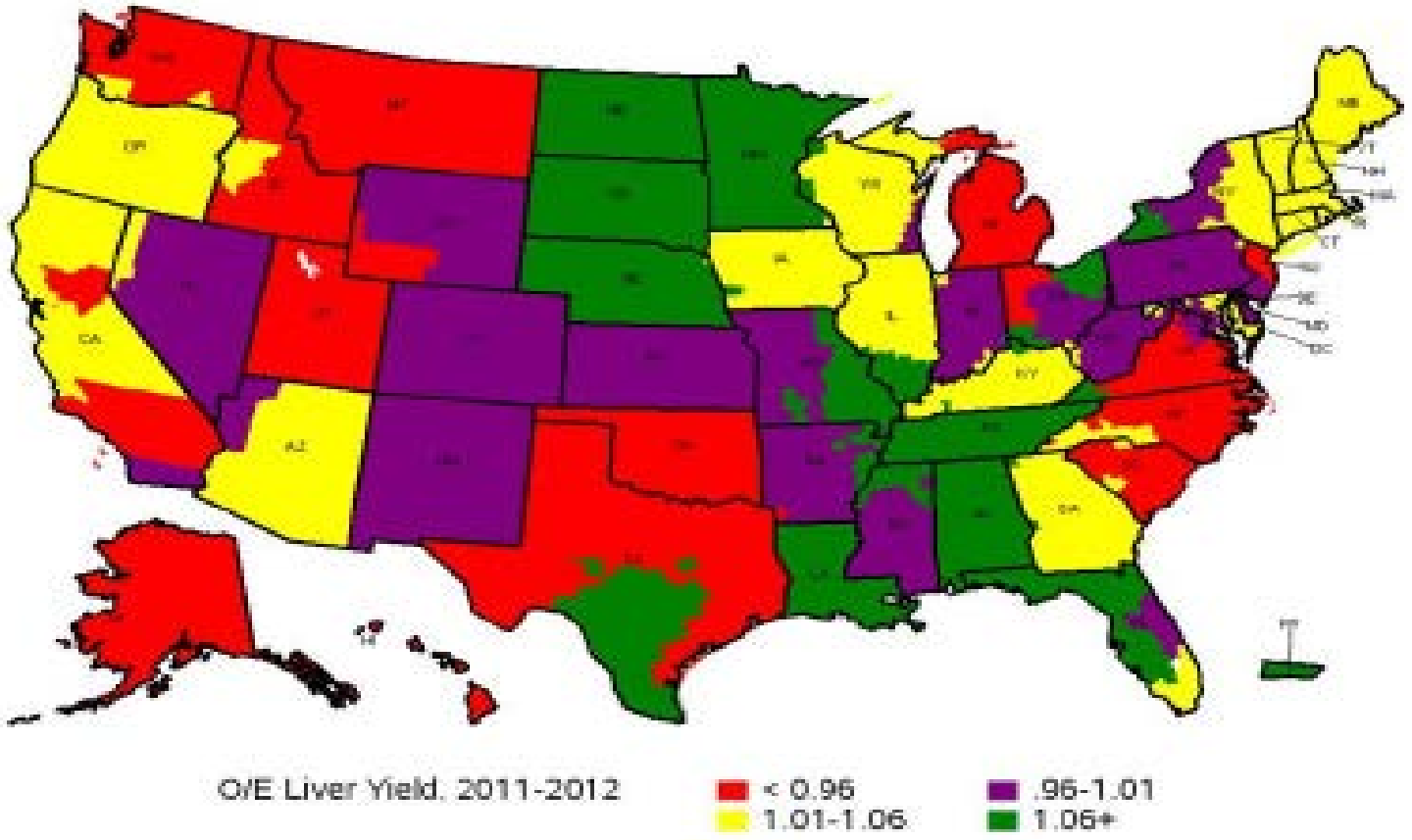
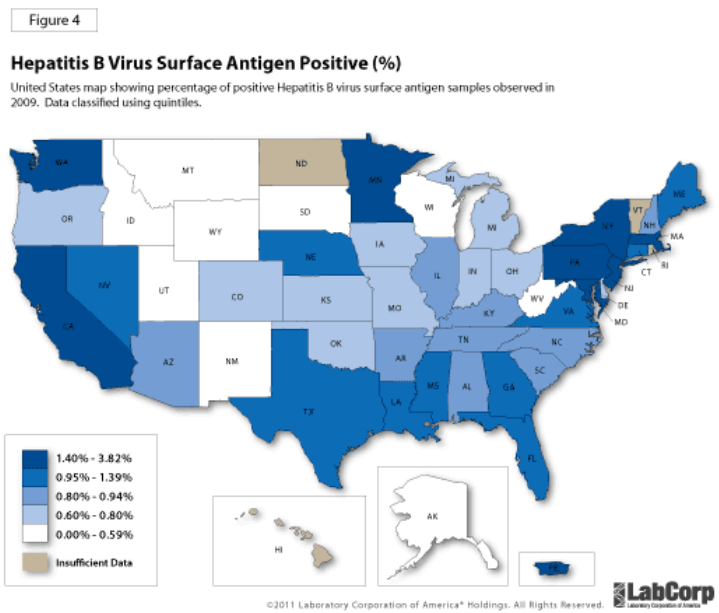
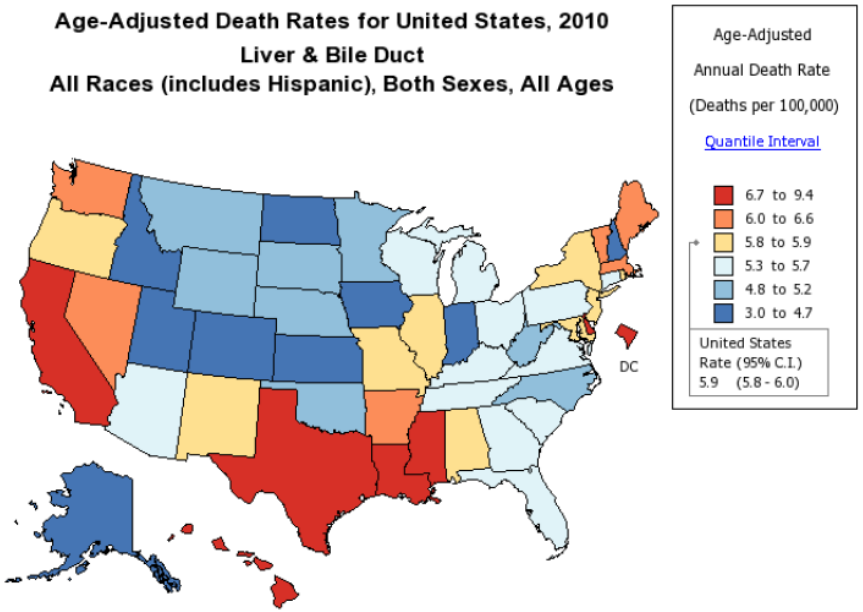


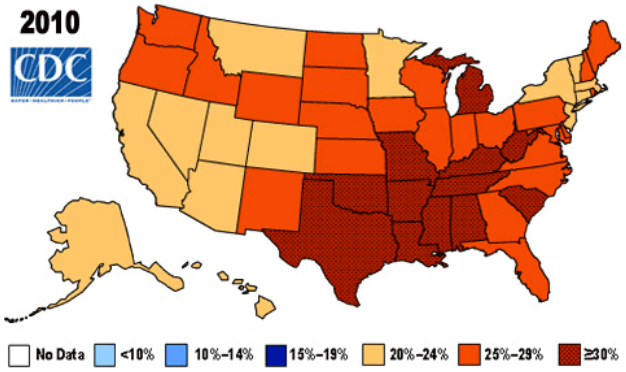
Figure 4: Observed to Expected Liver Yield, 2011-2012

Redesigning liver distribution to reduce variation in access to liver transplantation
https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf

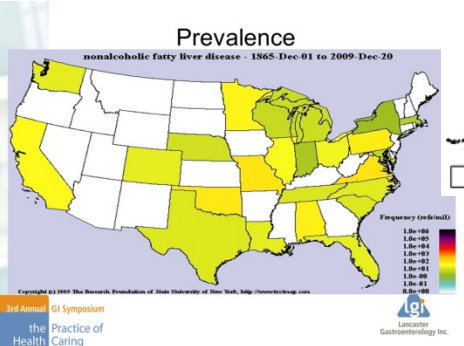
Liver disease is not equally distributed

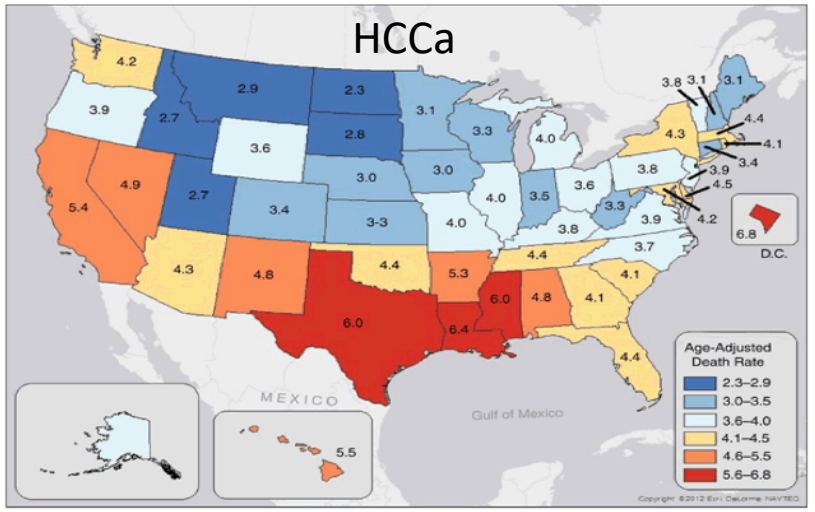






obesity





We are a heterogeneous country

Organ Allocation: §121.8(a) Policy development

- Policies for the equitable allocation of cadaveric organs…Such allocation policies:
  1) Shall be based on sound medical judgment;
  2) Shall seek the best use of donated organs;
  3) Shall preserve the ability of the transplant program to decline an offer…
  4) Shall be specific for each organ type (to patient);
  5) Shall be designed to avoid wasting organs, avoid futile transplants, promote patient access…, promote efficient management of…placement;
  6) Shall be reviewed periodically and revised as appropriate;
  7) Shall include procedures to promote and review compliance
  8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

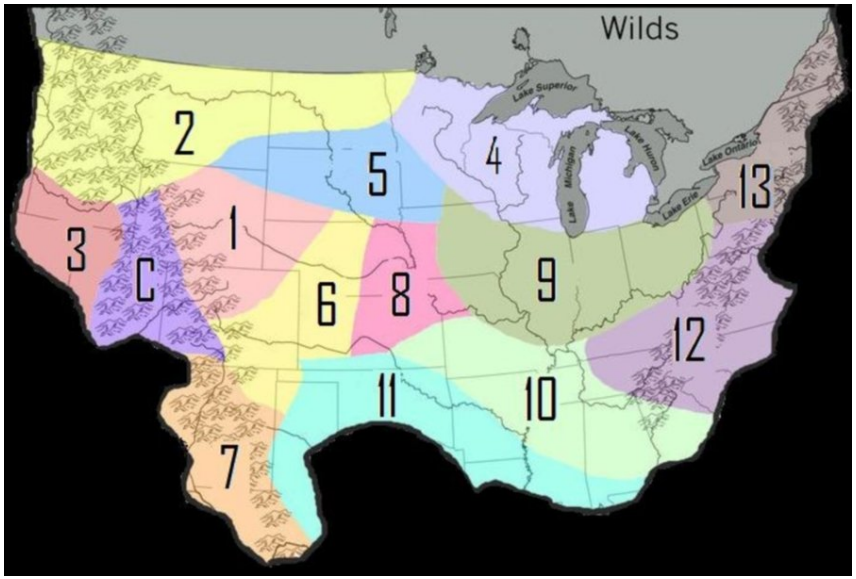
Does equalizing one variable really address our problem?

There are 5 allocation criteria in addition to geography

Shall be designed for best use of organs, avoid wasting organs, avoid futile transplants, promote patient access…, promote efficient management of…placement: place of residence or listing should not be a factor if the 5 criteria above are not impacted.

Liver Redistricting: this was a bad way to start talking about the problem

a term commonly used in conjunction with gerrymandering efforts designed for specific benefits.



How do you make your voice heard when no one seems to be listening?
Go outside the system.

Fixing problems from within or outside the “system”?

- Our current system was established so policy would be developed and made by those who understand the complexities of transplantation.
  - Shouldn’t be done by those not accountable to the patients waiting for an organ.
- Developing solutions to complex problems requires an understanding of many issues.
- When is it time to say the system doesn’t understand?
  - Apparently “now” judging by the way we’re acting and addressing issue.
- Going outside the process and asking the Godfather to “fix” your problems has consequences.
  - Neither congress nor the media understands the issues associated with organ allocation.

"Good. Some day, and that day may never come, I will call upon you to do a service for me. But until that day, accept this justice as a gift on my daughter's wedding day."

Don Corleone, *The Godfather*

Moral: asking for justice, when there are strings attached will often lead to misery.

Geographic MELD disparity at time of OLT: Allocation or Rationing? ***What's the issue***?

- HRSA, **CLARIFY** issues: is MELD disparity really the metric we want to normalize to achieve equitable allocation?
- OPTN/UNOS, rethink the **PROCESS**. Presenting the "solution" from atop a dais in a giant ballroom? Didn't we learn anything about community engagement, buy in and development from LYFT and kidney allocation process?
- Transplant community: **ENGAGE**. Know the rules. *Listen* to each other, don't just react. There are valid points on all sides. The problem is that there aren't enough livers and we have to make some hard decisions about who will live and die, which programs will thrive or shrink. Is the size of the pie fixed? If so, that has consequences.
  - Don't kiss the Godfather's ring. Taking our disagreements to Congress and the press will cause regret.
  - Despite frustration, keep the dialogue within the "family".

Issues with the organ shortage: is the size of the pie really fixed?

- Use what's available: 2.5+ million deaths, less than 10,000 donors? DDPS has over 35,000 in US.
  - Old people die more frequently than young people, don't expect heroin epidemic to be a consistent reason for deceased organs.
- We **must use organs** from older deceased donors. Will require a change in metrics and expectations.
  - Programs live and die by PSR. Are they right? Do they encourage/discourage organ use?
  - HRSA/SRTR/OPTN (insurers/CMS) and what we tell patients (manage expectations)
- Why not more live donors?
  - Remove disincentives: don't make live donors pay for their donation.
  - Manage the message

Shortage leads to desperation

American Journal of Transplantation 2017; 17: 577
Wiley Periodicals Inc.

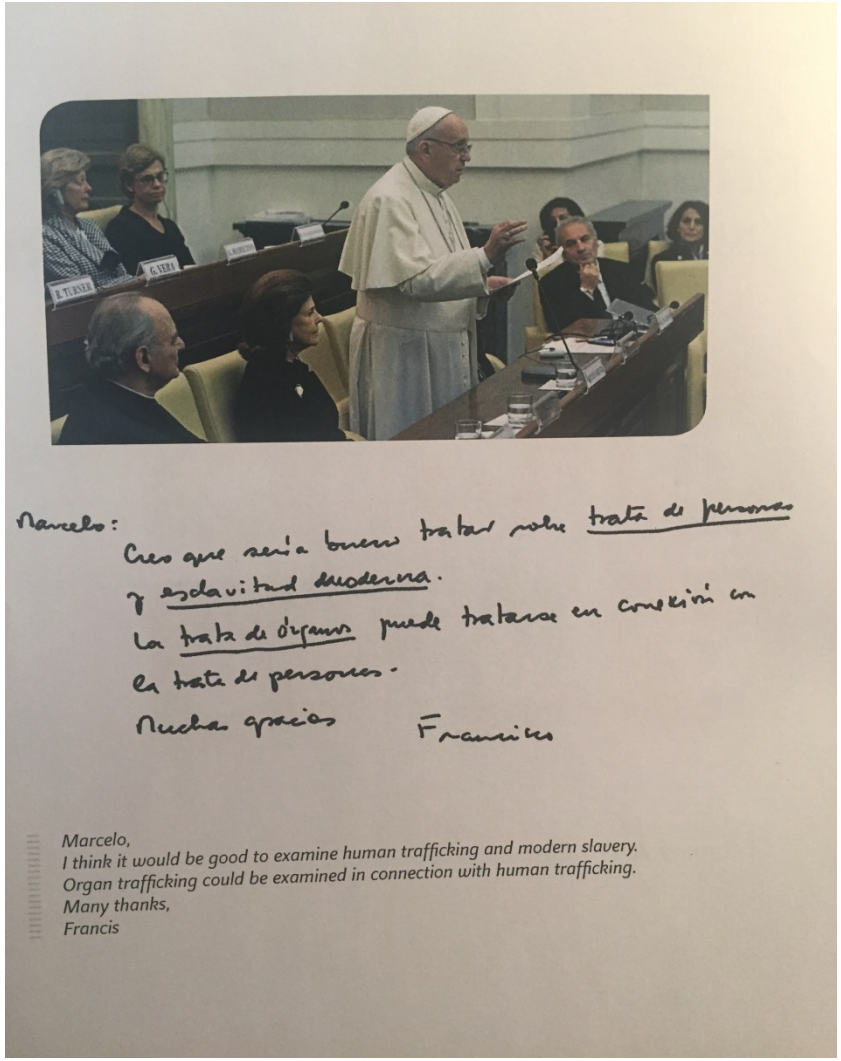
doi: 10.1111/ajt.14028

Letter to the Editor

Criminal Organ Retrieval: Unconscionable

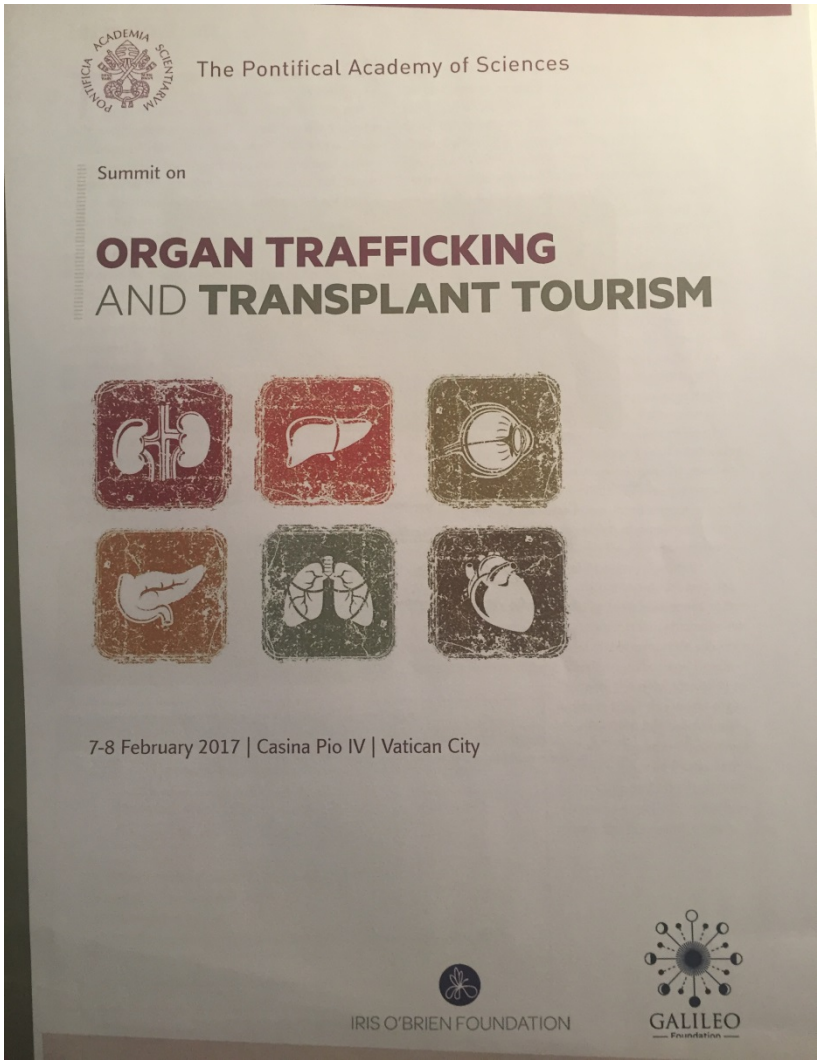
T. L. Pruett, President, American Society of Transplant Surgeons,
A. Vathsala, President, Asian Society of Transplantation,
T. Berney, President, European Society for Organ Transplantation,
J. Lerut, President, International Liver Transplantation Society,
J. S. Odorico, President, International Pancreas and Islet Transplant Association,
M. Johnson, President, International Society for Heart and Lung Transplantation,
H. Egawa, President, Japanese Society for Transplantation,
F. Gonzalez-Martinez, President, Latin American and Caribbean Society of Transplantation (STALYC),
M. Haberal, President, Middle East Society for Organ Transplantation,
N. L. Ascher, President, The Transplantation Society and
A. K. Chandraker, President, American Society of Transplantation

There are moral and ethical consequences surrounding (the lack of) organ availability



Marcelo:
Creo que sería bueno tratar sobre trata de personas y esclavitud moderna.
La trata de órganos puede tratarse en conexión con la trata de personas.
Muchas gracias Francisco

Marcelo,
I think it would be good to examine human trafficking and modern slavery.
Organ trafficking could be examined in connection with human trafficking.
Many thanks,
Francis



Pontifical Academy of Science, Feb 2017

Summit on Organ Trafficking and Transplant Tourism, Feb 7-8 in Vatican City

- Sixty-nine presentations, with reports from 50 countries/regions around the world.
- Conclusion: “need” for transplantable organs far, far exceeds the availability. http://www.transplant-observatory.org/
  - Roughly 120,000 organ transplants/yr worldwide
  - About 27,000 deceased organ donors/yr
- With such a significant gap between need and availability, an enormous opportunity exists for exploitation and abuse of vulnerable individuals.

Concluding Statement:

http://en.radiovaticana.va/news/2017/02/09/vatican_organ_trafficking_summit_issues_statement/1291387

- The overwhelming **global need for organs**, when *juxtaposed with large vulnerable populations (extreme poverty, migrants, prisoners) has resulted in immoral/illegal activities to obtain organs*.
  - Many examples of open solicitation of organs: Bangladesh, Pakistan others in impoverished neighborhoods; migrants incapable of meeting traffickers' demands; prisoners in China
  - Estimated that up to 10% of all global transplants are performed with illicitly obtained organs. Hard number to prove/disprove.
- The international **transplant community will NOT countenance the abuse of vulnerable populations**, specifically called out: prisoners. Also specifically states that paying families/individuals for organs is illegal.

Balancing demand and availability: why not let the market work?

THE WALL STREET JOURNAL.
WSJ

OPINION EUROPE

The Case for Paying Organ Donors

There is no indignity in financial gain.

By **SALLY SATEL**

Updated Oct. 18, 2009 8:00 p.m. ET

Last week the Council of Europe and the United Nations issued a joint study on trafficking in human organs. According to the study, up to 10% of all kidneys transplanted worldwide are obtained in the organ bazaars of Africa, Asia, Eastern Europe and South

OPTN | UNOS

Public Comment Proposal

A White Paper Addressing Financial Incentives for Organ Donation

OPTN/UNOS Ethics Committee

"This proposed white paper addresses potential financial incentives for both deceased and living organ donation…

Jan 2017

Taking advantage of the vulnerable through enticement is well recognized in our culture

- "Honest John" and Gideon entice Pinocchio to join Stromboli's puppet show and go to Pleasure Island.
- For money, fox and cat cajole Pinocchio to become a feature attraction in puppet show.
  - But once Pinocchio was in the show, it was a nightmare.
  - In Collidi's book, the brokers were self-serving, willing to kill Pinocchio for reward/money.
- Market models must anticipate that people will take advantage/misuse/harm those unable to "protect" themselves.

Life is complex and complexity is to be embraced as part of the greater whole

Natcher, teaching English in China

Transplant problems are complex, but the issues are interwoven

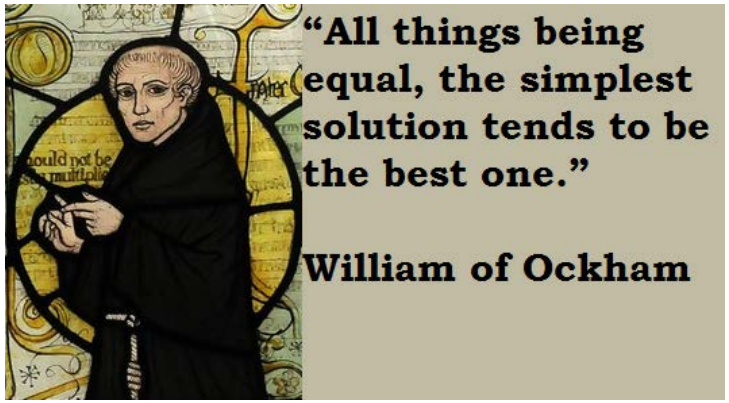
- Transplant issues are **multi-faceted**
- There are **many people** with divergent opinions
  - Oversimplification will rarely address the elements of a complex (transplant) problem.

- *Listen* to understand the issues, embrace complexity.
- *Understand* to establish relevance/priority of differing perspectives and values.
- Use relevance/priority to generating ideas to integrate (conflicting) *values that address the problems*.
- Without listening and understanding we will never get to our desired goal.
- Please, let's reintroduce our tradition of inclusicivity into the discussion of complex (transplant) problems.

ASTS Core Values: let's use them

http://asts.org/about-asts/mission-and-bylaws

- Integrity
- Excellence
- Forward Focus
- Respect
- Diversity: diversity is integral to the moral code by which we connect lives.
- Compassion: strive to emulate the generosity and courage of the donors and families who make transplantation possible and to offer hope to our patients.



There may not be a right answer, but there are wrong ones, Thank you