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Changing OPTN/UNOS Implementation Policies and Practices: Supporting Innovation in a Structured Environment

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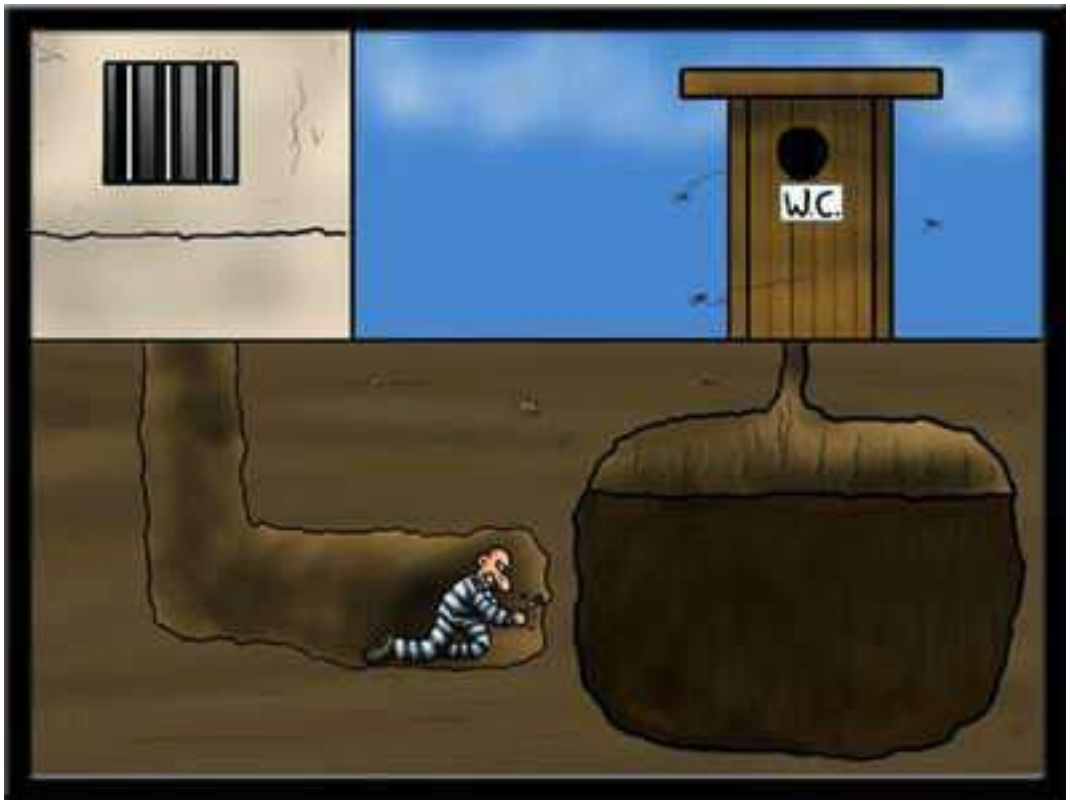
Disclosure

I have no financial or fiduciary relationships that would bias the content of this presentation.

So, for starters, let’s acknowledge it could be worse.



The current process has been successful.

- Kidney Allocation
- Simultaneous Kidney Pancreas Allocation
- Simultaneous Liver Kidney Allocation
- Liver Allocation
- MELD
- EPTS
- KDPI
- IT brought into the 21st century

However, the pertinent question is;
Can we do better?

More to the point: Does the current framework of policy development in the OPTN/UNOS prevent us from solving the future challenges in organ allocation?

- Evidence based allocation of organs to meet patient needs.
- Rationale prioritization of need.
- The multi-organ allocation hypocrisy.
- The appropriated distribution of a scare resource.

Problem #1: Our obsession with consensus.

In theory, policy development by consensus is great.

However, reality is somewhat different.

SLK policy development.

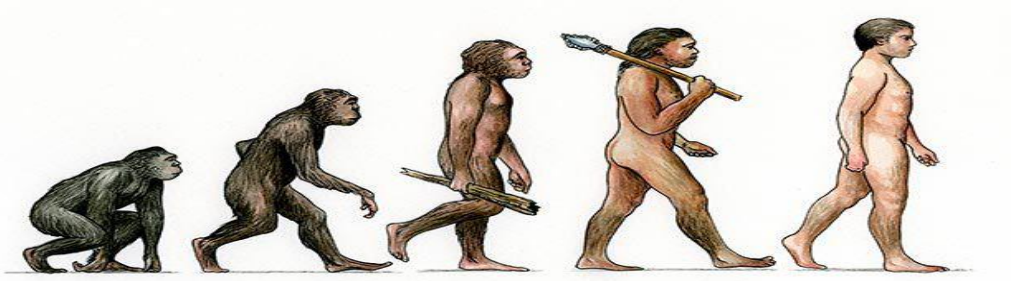
2006-2007—Societies hold consensus conference on the issue

2009—Kidney and Liver Committees sponsor public comment proposal

2010—Committees decide not to move forward due to complex IT programming (mostly due to kidney allocation variances) and development of new KAS

2013—KAS is approved by Board, SLK working group is formed

2014—KAS is implemented, removing all variances



Points to consider regarding policy by consensus.

- Who are we building consensus among, transplant centers or patients?

- Do all issues truly require a consensus?

- Consensus is a goal, not a requirement. A policy can be right even if it is not popular.

Audience Response question:

How important is consensus to policy development?

A. Critical and not to be sacrificed.
B. Valuable when it occurs but should not be a barrier.
C. Highly overrated, just tell us what to do.

Problem #2: Time.

For policy items that require public comment:
Do we really need 60 days?

- Most comments come in the first and last week. Honestly, if it were not for the last minute I would get nothing done.

- There are more contemporary ways to solicit opinions and build support for ideas, even bad ones. 

- Web based public forums will reach more people.

Audience response question:

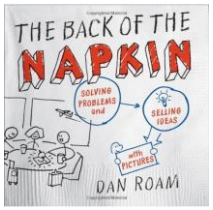
How long should the public comment be?

A. No change, 60 days.
B. Modify slightly to 30 days.
C. 2 weeks, just get to the point.

Problem #3: New ideas.

Currently there is only one pathway for new ideas – through committee.

- Some of the best ideas come from people just talking.



- The OPTN/UNOS should host think tanks and policy hack-a-thons.

TSAI CENTER FOR INNOVATIVE THINKING AT YALE

Yale Healthcare Hackathon

- The OPTN/UNOS should develop an *effective* pathway to receive, vet and develop promising new ideas regardless of the source.

Audience response question:

What is the optimal pathway for new ideas?

A. No change, the only good ideas come from committee.
B. Increase community input into the committies.
C. Doodle poll.

Problem #4: The one size fits all policy approach.

Currently, policy is implemented uniformly across all regions of the country and applied categorically to all patients.

- Is this a realistic assumption given the size, geography and diversity of this country?

- Pilot projects should be encouraged to study better ways to use and allocate organs. This should be accompanied by regulatory protections.

- Alternative allocation units and policies may be necessary to address inherent differences of geography and population density in the country.

To conclude:

- The highly structured and hierarchical nature of OPTN/UNOS policy development has served its purpose.
- The OPTN/UNOS needs to change with the times and the demands of the current challenges in organ allocation.
- The organ allocation challenges of the coming decade will require a less rigid and more creative approach to find policies and practices acceptable to the community.

Audience response question:

Should UNOS policy be tailored to local conditions?

A. What do you mean, transplant centers are all the same – no change.
B. Okay to modify policy for extreme differences, example Hawaii.
C. Policy should be tailored to the smallest possible unit.

The End