Context

The US organ transplantation system
Civics
Federal Government and Organ Transplantation

- Legislative – creates laws (gives authority)
  - e.g., National Organ Transplant Act (NOTA), amended
- Executive – implements those laws
  - e.g., OPTN Final Rule, OPTN policies
- Judicial – interprets the laws
  - e.g., challenges to the authority or interpretations of executive branch
Example: HRSA

U.S. Department of Health and Human Services
Establishes organ donation regulatory framework according to NOTA

HRSA

- Awards and oversees the contracts for the operation of the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR)
- Monitors OPTN/SRTR adherence to applicable statutes and regulations
- Funds grants and supports other activities aimed at increasing supply of donated organs and increasing efficiency of transplantation system

OPTN
SRTR
Other HHS Agencies involved in the Transplant System

• NIH - NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

• CMS – administers Medicare, Medicaid, and Innovation Center; provides education and outreach

• CDC - CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

• FDA - The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation
Foundation

National Organ Transplant Act
Organ Transplantation Statutory Authorities

• **National Organ Transplant Act** (NOTA) (P.L. 98-105, October 19, 1984), as amended, enables:
  - Organ Procurement and Transplantation Network (OPTN)
  - Scientific Registry of Transplant Recipients (SRTR)
  - Congressional report on the Scientific and Clinical Status of Organ Transplantation

• **The Charlie W. Norwood Living Organ Donation Act** (Norwood) (P.L. 110-144, Dec. 21, 2007) enables:
  - Enables and clarifies that organ paired donation is not valuable consideration
  - Congressional report on the Long-Term Health Effects of Living Organ Donation
Organ Transplantation Statutory Authorities

- **The Organ Donation and Recovery Improvement Act** (ODRIA) (P.L 108-216, April 5, 2004) enables:
  - **Public Education** – public and professional education to increase awareness of the need for organ donation and improve organ procurement practices
  - **Grant Authority** – public awareness grants to states and public entities
  - **Living Donor Assistance** – mechanism to provide reimbursement of travel and subsistence expenses for living organ donors
  - **Congressional Report** – Organ Donation and the Recovery, Preservation, and Transportation of Organs
NOTA 1984

• First part of NOTA was to set up a Task Force (TF) of 25 members
  • Physicians/non-physicians in transplant and OP, general public, non-physician social scientists, insurors
  • Ex-officio from government: Surgeon General, Leaders from NIH, FDA, and HCFA (CMS)

• Required to
  • Meet at least 3 times
  • Prepare a report on immune tolerance drugs (7 mos)
  • Prepare a report (12 mos) addressing
    • Conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation
    • Advise the secretary with respect to development of regulations for grants under sec 371 of the PHS Act
Framing

OPTN Final Rule
Regulatory Framework

The OPTN Final Rule (42 CFR, Part 121) provides regulatory requirements for:

- OPTN structure, membership, and function;
- Waiting list/match run, donor testing, organ packaging/labeling;
- OPTN policy making (particularly allocation of organs);
- OPTN oversight activities and performance indicators;
- Data collection and dissemination;
- Establishing the Advisory Committee on Organ Transplantation;
- OPTN membership requirements: organ procurement organizations (OPOs), transplant centers, Human Lymphocyte Antigen (HLA) labs; and
- Organ procurement, packaging, labeling, and transport
Finish Work: Transplant System

- OPTN Policies
- SRTR Contract
- Grants Program
- Transplant Centers
- Public Outreach
- NLDAC
- CMS Conditions of Participation
- Organ Procurement Organizations
- NIH Research
- CDC investigation
- FDA product approvals
- Private organizations
Everything Old is New Again

Themes from the TF Report and what we grapple with today
Building the Future of Transplantation

How do we build a transplant system that is innovative and gets more people transplanted?
We Need Radical Reconstruction
Access to Organs

- Number of Transplants Performed:
  - 1990: 1,000
  - 2000: 20,000
  - 2010: 30,000
  - 2015: 40,000

- Number of Donors Recovered:
  - 1990: 1,000
  - 2000: 10,000
  - 2005: 15,000
  - 2010: 20,000
  - 2015: 25,000

- Number of Patients Waiting at Year End:
  - 1990: 10,000
  - 2000: 60,000
  - 2005: 90,000
  - 2010: 120,000
  - 2015: 115,759

Note: The data is presented graphically with years ranging from 1990 to 2015.
SAVING LIVES WITH THE MOST-VIEWED NON-PROFIT AD EVER...
Winning strategy to:

“Provide hope, healing and life to as many people as possible as creatively as necessary.”
MOTIVATE THE MOST SELFISH SEGMENT OF THE POPULATION TO DO THE MOST SELFLESS ACT POSSIBLE
martin
“I DON’T WANT TO MAKE MONEY, I WANT TO MAKE A DIFFERENCE.”

- Lady Gaga
HOW DO YOU HAVE A CONVERSATION ABOUT DEATH?
WITH MILLENNIAL MEN.
I’M NOT A TOTAL ASSHOLE
I’M AN ORGAN DONOR
CAMPAIGN RESULTS

More than **50 million views** in the first week across U.S. social media and web

Total views now over **150 million**

Daily registrations currently averaging **400 per day**

**Top Google search** in the U.S. (08.05.16)
Campaign Results

56% (Male)

44% (Female)
NATIONAL DONATE LIFE REGISTRY ACTIVITY
BEFORE & AFTER CAMPAIGN LAUNCH

# REGISTRATIONS/DAY

BEFORE
149

AFTER
1040

+ 598%

% AGE 20-34

BEFORE
22%

AFTER
52%

+ 136%

% MALE

BEFORE
26%

AFTER
56%

+ 115%
OPOs and DSAs

Donation Service Areas
OPOs and DSAs

- Business model needs updating
- OPO community should grapple with this issue
- Creative ways to consolidate resources and improve efficiency
Outcomes Reporting

- There is too much focus on refining current metrics rather than on determining which data are most relevant and developing actionable metrics and better modes of presentation.
- Transplant stakeholders (patients and families, government, organ procurement organizations, and transplant centers) need to collectively step back and consider which data will drive improvements in transplantation.
• We should also consider which data are suited to the public domain, and which should be used to inform ongoing quality improvement.

• Most importantly, we should let our patients guide us in developing the patient-centered outcomes metrics they want to make informed decisions, and which will drive continued innovation and excellence in transplantation. Metrics should be developed accordingly, and those should comprise the “next generation” of program-specific reports for presentation to the public.
Research

• To facilitate success in clinical transplantation, it is essential to examine policies and regulations governing transplantation priorities may present unintended or poorly understood barriers to innovative research or to the coordination of clinical trials.

• In transplantation, as in other important areas in medicine (eg, oncology/stem cell transplantation, personalized medicine), research has been driven largely by the scientific community. The transplant community should be encouraged to identify innovative research priorities as a basis for clinical trials.

• A mechanism to address this need could include [recurrent] State of the Science Symposia, workshops that would review recent scientific advances in the field of organ transplantation and identify compelling opportunities for clinical research in the following several years.
Innovation Symposium Findings

1. Develop a roadmap for policy and research in organ transplantation, cosponsored by federal and nongovernmental stakeholders;
2. Examine how to best assess and report clinical outcomes metrics in the context of innovative research;
3. Define how metrics for innovative research are used by the OPTN and CMS for reporting of transplantation outcome measures;
4. Create a mechanism to identify and facilitate innovative research that crosses traditional boundaries within transplantation; and
5. Harmonize performance metrics between OPO, clinical transplant centers, and possibly other stakeholders (eg, third-party payers).
Developing Innovative Ideas

• Think of organ donation and transplantation as a system rather than isolated component parts
• Set a goal and work with a deadline
• Work with people outside your immediate field – include multiple viewpoints from the beginning
• Think in terms of what the ideal solution would look like – not what is the current system or what are the constraints we have ---
  • Easier to ask for what you want when you can describe what it is
  • Within systems averse to change, it can be easier to move toward a vision that is clearly beneficial and understandable
  • When there is a specific goal in mind, people expert in those areas can often sort out how to get over (or around, or under, or simply remove) the hurdles
In Conclusion

The US has one of the best transplant systems in the world

We can and MUST make it better

Our patients’ lives depend on it
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