The State of Transplant Quality and Regulatory Management

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Disclosure

- Consultant with XYN Management for XYN QAPI
Objectives

- Describe the evolution of the focus on quality and outcomes in transplantation
- Identify barriers to embracing the focus on quality and outcomes
- Analyze impact of increased scrutiny on transplant programs
- Discuss improvements from this focus on quality
Describe the evolution of the focus on quality and outcomes in transplantation
What happened? LA Times?

- LA TIMES INVESTIGATION
  - 20% of U.S. Transplant Centers Are Found to Be Substandard

U.S. organ network routinely fails to detect problems.
By Charles Ornstein and Tracy Weber
October 22, 2006

Hospital's Kidney Transplant Death Rate Raises Concerns
December 17, 2005 | Charles Ornstein, Alan Zarembo and Tracy Weber | Times Staff Writers
Enter Senator Grassley

2005 GAO reported that transplant programs were not adequately regulated
Enter:
CMS, OPTN, SRTR
Fig. 1
Federal organization chart for organ transplantation. *Private, non-for-profit entity under federal contract. (With permission from UNOS)
Number of Medicare-Approved Transplant Hospitals

Number of Transplant Hospital Centers

Pink: 0
Orange: 1-9
Green: 10-20
Blue: 21-30
<table>
<thead>
<tr>
<th>Proposal</th>
<th>Sponsoring Committee</th>
<th>Status</th>
<th>Open for Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enhancing liver distribution</strong></td>
<td>Liver and Intestinal Organ Transplantation Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Improving en bloc kidney allocation 2</strong></td>
<td>Kidney Transplantation Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Improving dual kidney allocation</strong></td>
<td>Kidney Transplantation Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Deceased donor initiated KPD chains</strong></td>
<td>Kidney Transplantation Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Living donation by persons with certain fatal diseases</strong></td>
<td>Ethics Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Review of HLA tables</strong></td>
<td>Histocompatibility Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
<tr>
<td><strong>Revise transplant fellowship training program approval bylaws</strong></td>
<td>Membership &amp; Professional Standards Committee</td>
<td>Public Comment</td>
<td>7/31/2017 - 10/2/2017</td>
</tr>
</tbody>
</table>
Transplant Center Search Results

For more help on choosing a transplant center, read How do I compare transplant centers?

<table>
<thead>
<tr>
<th>Center Name</th>
<th>Location</th>
<th>Recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within 50 miles of 20037</td>
<td>Adult</td>
</tr>
<tr>
<td></td>
<td>OR Select State</td>
<td></td>
</tr>
</tbody>
</table>

Showing 9 results for kidney transplant centers, adult patients, within 50 miles of 20037

Click column headers below to sort the results by distance, transplant rate, transplant volume, or by outcome assessment:

<table>
<thead>
<tr>
<th>NAME</th>
<th>DISTANCE</th>
<th>TRANSPLANT VOLUME</th>
<th>TRANSPLANT RATE</th>
<th>OUTCOME ASSESSMENT</th>
</tr>
</thead>
</table>

OUTCOME ASSESSMENT
The outcome assessment is a risk-adjusted assessment evaluating how often patients are alive with a functioning transplanted organ 1 year after transplant. The assessment is assigned after case-mix adjustment for the types of recipients who undergo transplant at the program and the donors used by the program. Programs are placed in the better or worse than expected category if we have 97.5% or greater probability that their outcomes are better or worse than expected based on national norms, respectively; otherwise they are placed in the “As Expected” category. Search results are sorted by adult outcome assessments then by Transplant Volume by default, so programs with the best assessments appear at the top of the list. You can choose to view assessments for pediatric recipients from the recipient drop-down list above; however, SRTR may not evaluate outcomes for pediatric recipients if too few transplants are performed. Click here for more information. You may also evaluate this data using the 5-tier system.
Transplant Surveys

- **UNOS**
  - Planned 3 day site visits
  - List of patients given 1 month ahead
  - Follow up with desk audits
  - All go to MPSC for decisions

- **CMS**
  - Unannounced visit
  - Usually 3-7 days
  - Focus is on quality, performance improvement and outcomes

- **UNOS**
  - Living donor surveys
  - List of donors and recipients
  - 3 day site visits

- **CMS Focused QAPI**
  - Unannounced visit
  - 2 surveyors, 2 days
  - Focus on QAPI
    - 10 pilots in 2013
    - 1 post SIA January 2014
    - Plan is for 2 surveys per week
      - Initial focus on programs in post SIA

- **Joint Commission**
  - Disease Specific programs
  - VAD (planned visits)
  - Lung
  - Not deemed authority for transplant yet
Identify Barriers to Embracing the Focus on Quality

1. Too much government oversight
2. Unclear directions
3. Disbelief
4. No need to make a change
5. Lack of knowledge about processes
Organ Transplantation: The First Government Takeover of Health Care

John R. Lake, MD
Professor of Medicine and Surgery
University of Minnesota Medical School
What did we feel like?
Some did not believe CMS would survey transplant programs
Some said “we are not doing this because we are fine....”

The most dangerous phrase in the language is "we've always done it this way."
Knowledge Deficit
Analyze impact of increased scrutiny on transplant programs

Financial
Staffing
Surveys
Data analysis
CMS Predicted Financial Impact

We believe this rule will neither increase nursing workloads nor create significant burdens for centers, including kidney centers. We estimate that on average, the cost for each currently-approved Medicare transplant center to comply will be less than $56,000 in the first full year following the effective date of the final rule and less than $21,000 in subsequent years.

Source: https://www.federalregister.gov/d/07-1435/p-25
What financial impact have Regulatory requirements had on transplant centers?

Increased Surveys
- Pre-emptive survey consultants

Systems improvement Agreements

Focus on Quality and Process Improvement

Thorough Analysis/RCA
Many of us began to study quality and outcomes

- American Transplant Congress/Transplant Management Forum/The Practice of Transplant Administration Workshop
  - Classes from SRTR
- Classes on Quality (Transplant Quality Institute)
  - Classes on Data Management
- College classes on Quality
- Hospitals preparing staff on Six Sigma
Some were educated by CMS and an SIA
What has been the impact on Staffing with the focus on quality and outcome?

- Programs began hiring additional staff:
  - Data coordinators
  - Data analysts
  - QAPI/Regulatory managers
  - Statisticians
  - Auditors
What has been the impact on staffing with the additional oversight?

- **UNOS**
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Has there been a steep learning curve?
Our learning curve about the crucial importance of accurate data entry and analysis
What have we learned about Data Entry?

- SRTR Risk adjustments need to be utilized

- Clinical understanding is needed
  - Patient diagnosis when listed
    - Should be agreed upon in patient selection
    - Some diagnoses carry a higher risk rate
  - Ethnicity
    - Patients should be asked to select from the UNOS ethnicity list
## Risk adjustment model for hearts

<table>
<thead>
<tr>
<th>Element Type</th>
<th>Element</th>
<th>TCR/DDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Candidate (at listing)</td>
<td>Any Previous Malignancy</td>
<td>TCR</td>
</tr>
<tr>
<td>Candidate (at listing)</td>
<td>Diabetes</td>
<td>TCR</td>
</tr>
<tr>
<td>Candidate (at listing)</td>
<td>Highest Education Level</td>
<td>TCR</td>
</tr>
<tr>
<td>Candidate (at listing)</td>
<td>History of Cigarette Use</td>
<td>TCR</td>
</tr>
<tr>
<td>Candidate (at listing)</td>
<td>Race</td>
<td>TCR</td>
</tr>
<tr>
<td>Donor</td>
<td>ABO Blood Group</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Age (years)</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Anti-CMV</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Anti-HBc</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Antihypertensives</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>BMI (kg/m², calculated from height and weight)</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>BUN (mg/dL)</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Cancer at the Time of Procurement: Intracranial</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Cause of Death</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Cigarette Use (&gt; 20 pack years) - Ever</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Clinical Infection</td>
<td>DDR</td>
</tr>
<tr>
<td>Donor</td>
<td>Clinical Infection of the Blood (Confirmed or Unconfirmed)</td>
<td>DDR</td>
</tr>
</tbody>
</table>
Candidate Registration form

Ethnicity/Race: * (select all origins that apply)

American Indian or Alaska Native
- American Indian
- Eskimo
- Aleutian
- Alaska Indian
- American Indian or Alaska Native: Other
- American Indian or Alaska Native: Not Specified/Unknown

Black or African American
- African American
- African (Continental)
- West Indian
- Haitian
- Black or African American: Other
- Black or African American: Not Specified/Unknown

Native Hawaiian or Other Pacific Islander
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Native Hawaiian or Other Pacific Islander: Other
- Native Hawaiian or Other Pacific Islander: Not Specified/Unknown

Asian
- Asian Indian/Indian Sub-Continent
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Asian: Other
- Asian: Not Specified/Unknown

Hispanic/Latino
- Mexican
- Puerto Rican (Mainland)
- Puerto Rican (Island)
- Cuban
- Hispanic/Latino: Other
- Hispanic/Latino: Not Specified/Unknown

White
- European Descent
- Arab or Middle Eastern
- North African (non-Black)
- White: Other
- White: Not Specified/Unknown
Why is risk adjusted data so important?

- Risk adjusted
  - Diabetes
  - Hypertension
  - Peripheral vascular disease
  - Prior transplants
    - Receive extra points in the formula used to derive each center’s expected survival rates
Understanding SRTR as part of the learning curve

- Education about SRTR
  - O:E ratios
  - Bayesian stats
    - (And CUSUM reports)
    - (And risk adjustments)
Why CUSUM???

- SRTR Program Specific Reports
  - Based on 2.5 year cohorts

- CUSUM Charts
  - Based on current one year outcomes
  - Not a true indicator of flagging, BUT
  - Maintained on your secure SRTR site
  - Not available to the public, CMS or MPSC
CUSUM Charts: Trends in current performance

- CUSUM is used to detect and demonstrate a change in a process by plotting performance over time
  - Each day without a death or graft loss the line goes down
  - Remaining close to Zero on the chart indicates you are performing at an expected rate
  - As the line goes up you are experiencing graft losses or patient deaths
  - Uses most current risk adjustment models for each program
Discuss improvements with this focus on regulations and quality
Collaborative Efforts between OPTN and CMS

- Collaborated to
  - Clarify CMS requirements similar to UNOS/OPTN policies
  - Create a crosswalk that allows programs to compare regulations
  - Create an ABO template form to assist with ABO verification compliance
  - Living Donor Survey Changes
  - CMS developed a webinar series presented through AST/ASTS
  - Attempted a 2016 version of interpretive guidelines
    - Withdrawn following major questions from the transplant community
What has happened since 2007?

<table>
<thead>
<tr>
<th>Organ</th>
<th>CY 2007</th>
<th>CY 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Kidney – graft survival</td>
<td>92.9%</td>
<td>94.8%</td>
</tr>
<tr>
<td>Adult Kidney – patient survival</td>
<td>96.4%</td>
<td>96.9%</td>
</tr>
<tr>
<td>Adult Heart – patient survival</td>
<td>88.5%</td>
<td>89.5%</td>
</tr>
<tr>
<td>Adult Liver – patient survival</td>
<td>87.7%</td>
<td>90.8%</td>
</tr>
<tr>
<td>Adult Lung – patient survival</td>
<td>80.4%</td>
<td>85.7%</td>
</tr>
</tbody>
</table>
What are some of the Transplant Center Concerns?

- Transplant Centers must meet expected outcomes established by CMS
  - Threshold was 1.5 for O/E has now been increased to 1.85
    - Had to cross all three thresholds:
      - O/E > 1.5
      - O-E > 3.0
      - One sided p value < 0.05
  - O/E of 1.5 meant that patient deaths or graft failures were 150% of the risk adjusted expected
  - When programs are flagged, waiting times for patients go up
How does organ donation enter into the equation?

- CMS created a Push-Pull between transplant centers and OPOs

- OPOs are regulated by CMS and OPTN as well
  - OPOs are being held to a specific threshold

- Transplant centers decreased transplanting
  - Older candidates (no risk adjustment)
  - Heavier patients (no risk adjustment)
Has the OPTN increased scrutiny?

- Based on transplant programs’ 1-year graft survival and 1-year patient survival hazard ratios, programs will be placed in the tier that corresponds with the worse result of these two analyses.

- **Quality Control Tier**: >60% probability that hazard ratio > 1.75
  - 100% probability of MPSC engagement

- **Quality Improvement Tier 2**: >60% probability that hazard ratio > 1.25, and the program is not included in the Quality Control Tier
  - 50% probability of MPSC engagement

- **Quality Improvement Tier 1**: hazard ratio > 1.0, and the program is not included in the Quality Control Tier or Quality Improvement Tier 2
  - 10% probability of MPSC engagement

- **Performing As Expected or Better Tier**: hazard ratio ≤ 1.0
  - 0% probability of MPSC engagement
CAUTION!

Unintended Consequences Ahead
Have there been unintended consequences of the regulations?

- **Risk Aversion**
  - Many centers have become more conservative/risk averse
    - Perform fewer transplants
    - Patients wait longer
      - Become sicker
      - Die on waitlist
    - May decrease access to transplant for:
      - Highly sensitized patients
      - High risk patients

- **Focus on Quality**
  - Quality and outcomes are focused on one year
    - No long term trends are being monitored
    - Patient reported outcomes are not a focus
Have there been unintended consequences of the regulations?

- **Clinical**
  - Limitations to risk adjustment methods
    - Single adjustment at age >55
      - 56 is same adjustment as age 80
    - No cardiac risk adjustment for kidney patients
  - Not accounted for:
    - Participation in paired exchange programs
    - ABO incompatible
    - Highly sensitized patients

- **Financial**
  - While outcomes have improved cost has been great to transplant centers without added funding or reimbursement
What does the transplant community consider as down sides of CMS COPs?

- Too much government oversight
- Policies and regulations are often prescriptive
- Unfunded mandates
  - Amount of data collection
  - Quality and outcome monitoring
    - Steep learning curve
  - Increased staffing
- Dual regulations from OPTN and CMS
  - Duplication of efforts
  - Inefficiencies
  - Site surveys from both
  - Inconsistency with surveyors
    - Interpreting interpretive guidelines
- Threat to innovation
  - Research, ABOi, highly sensitized patients
What are the positive aspects about CMS COPs?

- **Provide**
  - Structure to a program
  - Guideline for developing new programs
  - Guidelines for improving programs

- **Require**
  - Thorough analysis of patient deaths, graft failure, living donor adverse event
  - Multidisciplinary team approach
  - Documentation
    - Inpatient
    - Discharge
    - Ambulatory care
  - Require us to follow policies
References


Any Questions?