# Regulatory Aspects of Transplant Management: OPTN, CMS and Payors

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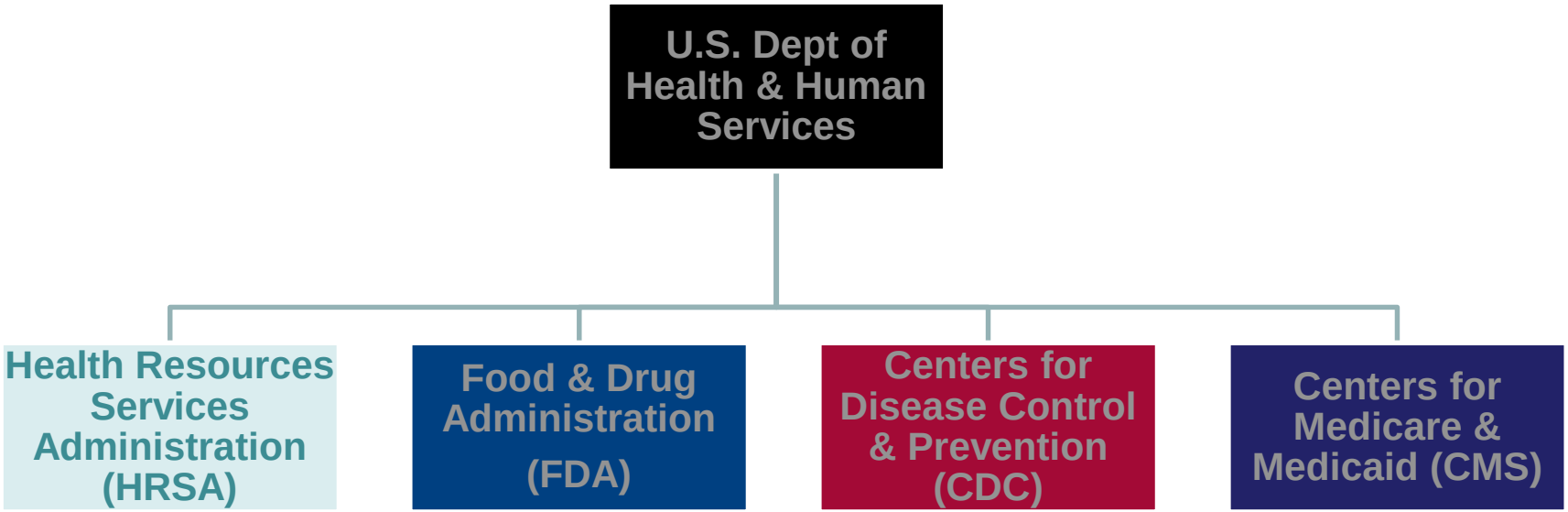


Organ Donation & Transplantation System

Tissue Donation

Disease Transmission / Patient Safety

Payment & regulates hospitals & providers

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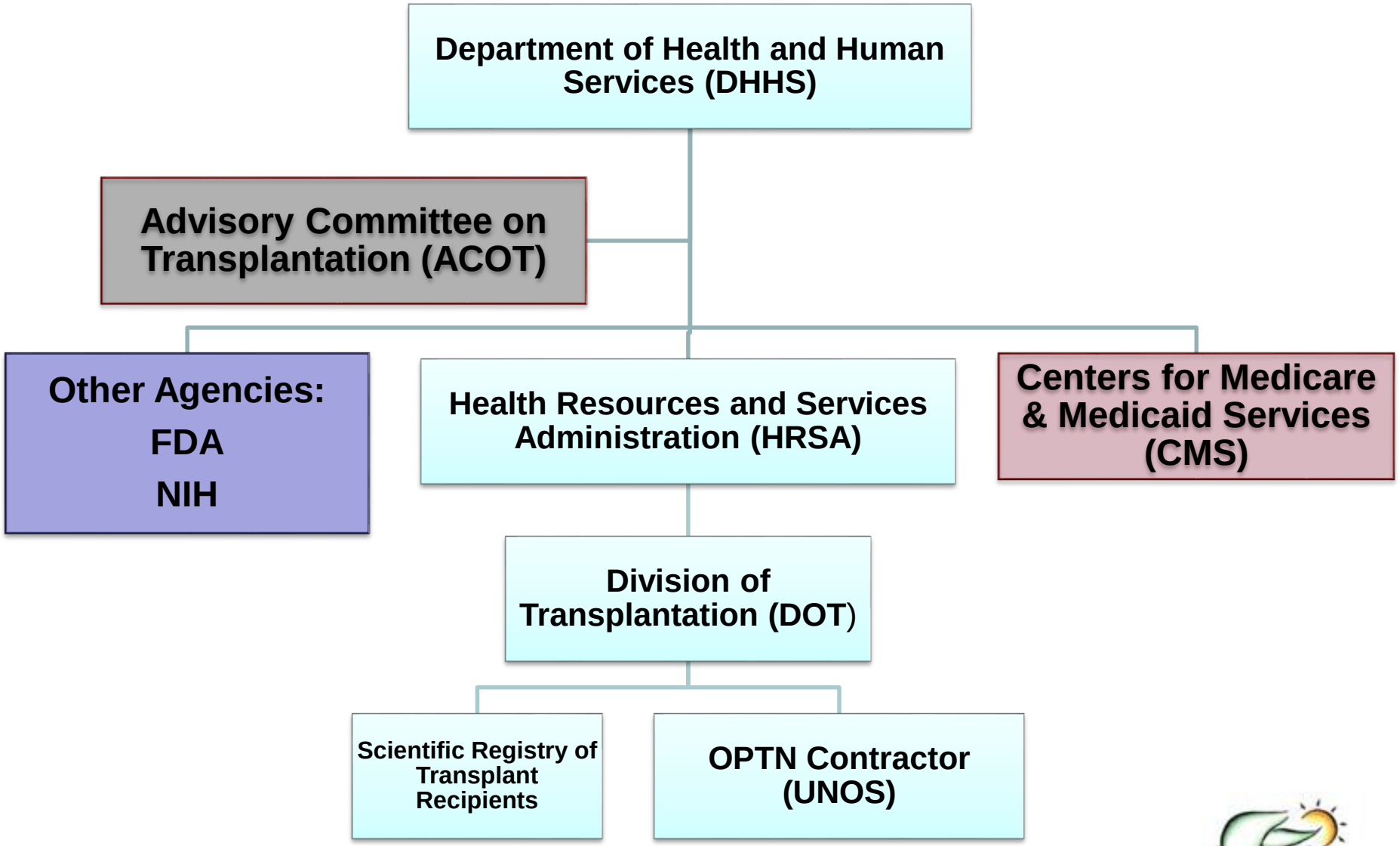
Department of Health and Human Services (DHHS)
Advisory Committee on Transplantation (ACOT)
Other Agencies:
FDA
NIH
Health Resources and Services Administration (HRSA)
Centers for Medicare & Medicaid Services (CMS)
Division of Transplantation (DOT)
Scientific Registry of Transplant Recipients
OPTN Contractor (UNOS)

# Organ Procurement and Transplantation Network OPTN

- NOTA 1984 validated organ transplantation, established the OPTN to allocate deceased donor organs throughout the country in an equitable and medically effective manner.
  - Standardize listing criteria
  - Standardize urgency criteria
  - Effective use of the donated organs
  - Organs for transplantation a “scarce national resource”
  - Buying and selling organs for transplant-illegal

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# OPTN

- OPTN develops policy and provides oversight of policy implementation in transplant centers
- Reviews Transplant programs Q 3years

# UNOS

- Private non-profit government contractor.
- Awarded the contract to administer the OPTN
- Manage organ allocation in the US through the organ center, DonorNet.
- Collect data on every transplant in the US.

# OPTN Final Rule

- Section 1138 of Social Security Act applies to transplant hospitals and OPOs and requires compliance
- OPTN Policies should address:
  - Equitable cadaver organ allocation
  - Prevention of transmissible diseases
  - Surgeon and physician training for transplantation; as pertains to center performance

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# OPTN Final Rule

- OPTN to review, evaluate and enforce
  - Review membership applications and compliance of members (not individuals) with policies and bylaws
  - If review finds that a member is acting in a fashion that violates OPTN policy or poses a risk to the health of patients or public safety, then recommend disciplinary actions to the Secretary of HHS.
- Membership and Professional Standards Committee is the peer review arm of OPTN

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# What the Final Rule does and doesn't address about you

- OPTN does not certify or credential individual surgeons.
- However, to be named the primary surgeon or physician for a specific organ at a member center, currency of experience in that procedure must be demonstrated through training or case load.
- The outcomes of individual surgeons are not followed or recorded in the SRTR. But surgeon data can be entered and used by centers.

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# Center for Medicare and Medicaid Services CMS

- Medicare  Final Regulation - Effective June 28, 2007.

- In order for hospitals to participate in Medicare and Medicaid reimbursement, they must follow the CMS Conditions of Participation.

# CMS and Transplant Center Conditions of Participation

- CMS has overall responsibility for these government programs.
- Lack of compliance can result in loss of Medicare reimbursement.
- Potential of problems with CMS captures the attention of hospital administrators

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# CMS

- Reimburses certified transplant centers at cost for a substantial amount of direct and indirect operation in organ acquisition
- Is the best payor for any transplant hospital system
- Audits transplant programs every 3 years or sooner for patient grievances

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# Scientific Registry for Transplant Recipients

- Obtains data from OPTN and CMS
- Provides data analysis and simulation models
- Acts as decision support to the OPTN board of directors
- Publishes center specific reports every 6 months

# Outcome Monitoring

- Outcome monitoring has existed for transplantation for many years.
- Centers of Excellence
  - Payor designation of centers
- SRTR reports of observed vs. expected outcomes
  - Publically reported
  - Used by OPTN as a trigger for peer review process

# What Are The Uses Of The PSR?

- Used by both the OPTN and CMS in center evaluation
- OPTN process is meant to be a peer-review process and not generally punitive.
- CMS process can result in center closures.
- Payors may drop centers with results significantly below expected. Can cost a busy center millions of dollars

# How Are Poorly Performing Centers Identified?

- Observed vs. Expected outcome calculated
- The centers submit data on recipients and living donors and the organ procurement organizations submit data on donors.
- Multi-variate Cox models are created that compare expected patient and graft outcome based upon the collection of all data submitted (national data) to the observed data at the center based upon individual patient characteristics

# US Hospitals with Liver Transplant Centers

California

| | | Before Transplant (as of 6/30/11) | | Transplant (7/1/10 - 6/30/11) | | | After Transplant (7/1/08 - 12/31/10) | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Waiting List | | Donor Type | | Recipient Age | Patient Survival Rate - One Year | | |
| State | Hospital | Number of Candidates | Median Wait Time | Living | Deceased | 18 & Over | Under 18 | 18 & Over | Under 18 | View Report |
| CA | California Pacific Medical Center, San Francisco, CA | 471 | >72 months | | 66 | 66 | 0 | 91% AS EXPECTED | Not Applicable | Report |
| CA | Cedars-Sinai Medical Center, Los Angeles, CA | 347 | >72 months | | 53 | 53 | 0 | 92% AS EXPECTED | Not Applicable | Report |
| CA | Childrens Hospital Los Angeles, Los Angeles, CA | 56 | 2 months | 11 | 14 | 0 | 25 | Not Applicable | 97% AS EXPECTED | Report |
| CA | Loma Linda University Medical Center, Loma Linda, CA | 195 | >72 months | | 35 | 35 | 0 | 76% AS EXPECTED | Not Applicable | Report |

**2010 Annual Report**

- Annual Report
- Survival Rates
- Chapters
- Data Tables

**Transplant Data**

- Transplant Program Reports describe the activity and outcomes at each transplant center in the US.
- Background and Methodology
- Risk-Adjustment Models (Transplant Programs)
- Risk-Adjustment Models (OPO)
- Upcoming Program Reports
- FAQs

**Contact the SRTR**

# Risk Adjustment

- Neutralizes the effect of higher risk donor and recipient selection on post transplant outcome for factors measured
- Risk adjustment may allow for the transplantation of higher risk recipients and use of higher risk donors

# Post-Transplant Survival Model: Covariates

(Order of Relative Import)

- Recipient factors
  - re-transplant; life support; malignant neoplasms other than HCC; functional status; portal vein thrombosis, recipient age>65; HCV; recipient age 60-64, abdominal surgery; creatinine, albumin;
- Donor factors:
  - donation after cardiac death, split liver; donor age>70, ischemic time>12 hours; Ischemic time 9-11 hours; race, cause of death

# CMS Conditions of Participation

- Centers whose observed graft or patient survival was below expected at risk for adverse action.
- Adverse action could mean loss of Medicare certification
- Loss of certification impacts center of excellence status and therefore loss of patients from private payors

# CMS Sequelae of Flagging

- Condition-level center deficiency
  - Flagged in current reporting period
  - Flagged at some other point in the last 2 years
- After 210 days (only ~20% new patients) one of the following occurs:
  - Outcomes improve
  - Mitigating factors are approved
  - A systems improvement agreement is implemented
  - Medicare participation is terminated

# Program Specific Reports

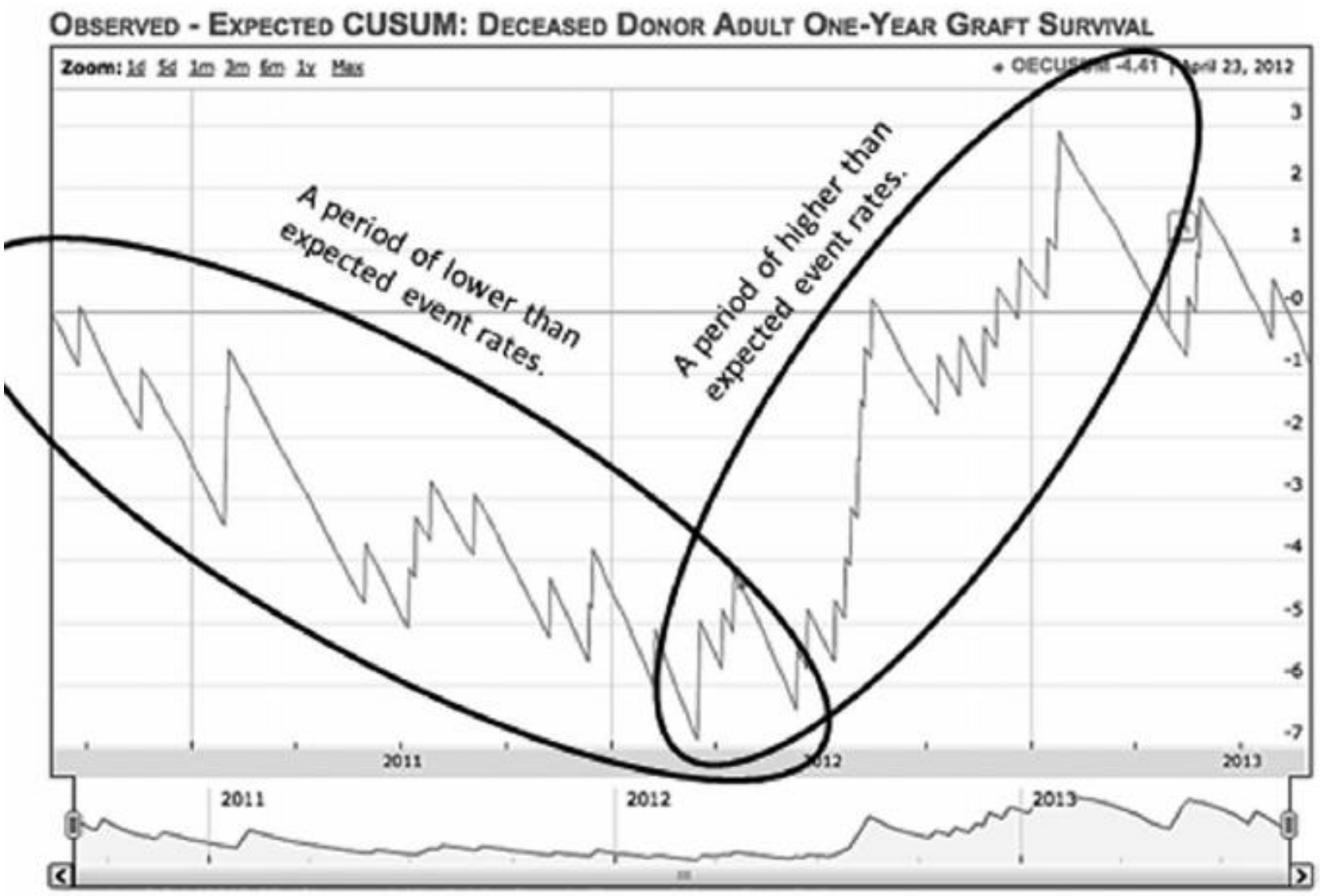
- When centers are flagged site visits by CMS and OPTN occur
- Center puts into place corrective action plan (CAP)
- Outcomes are observed looking for change in flag.
- Cohorts are 2.5 years in duration so time to change is very slow
- If flag still present, another round of CAP

# CUSUM

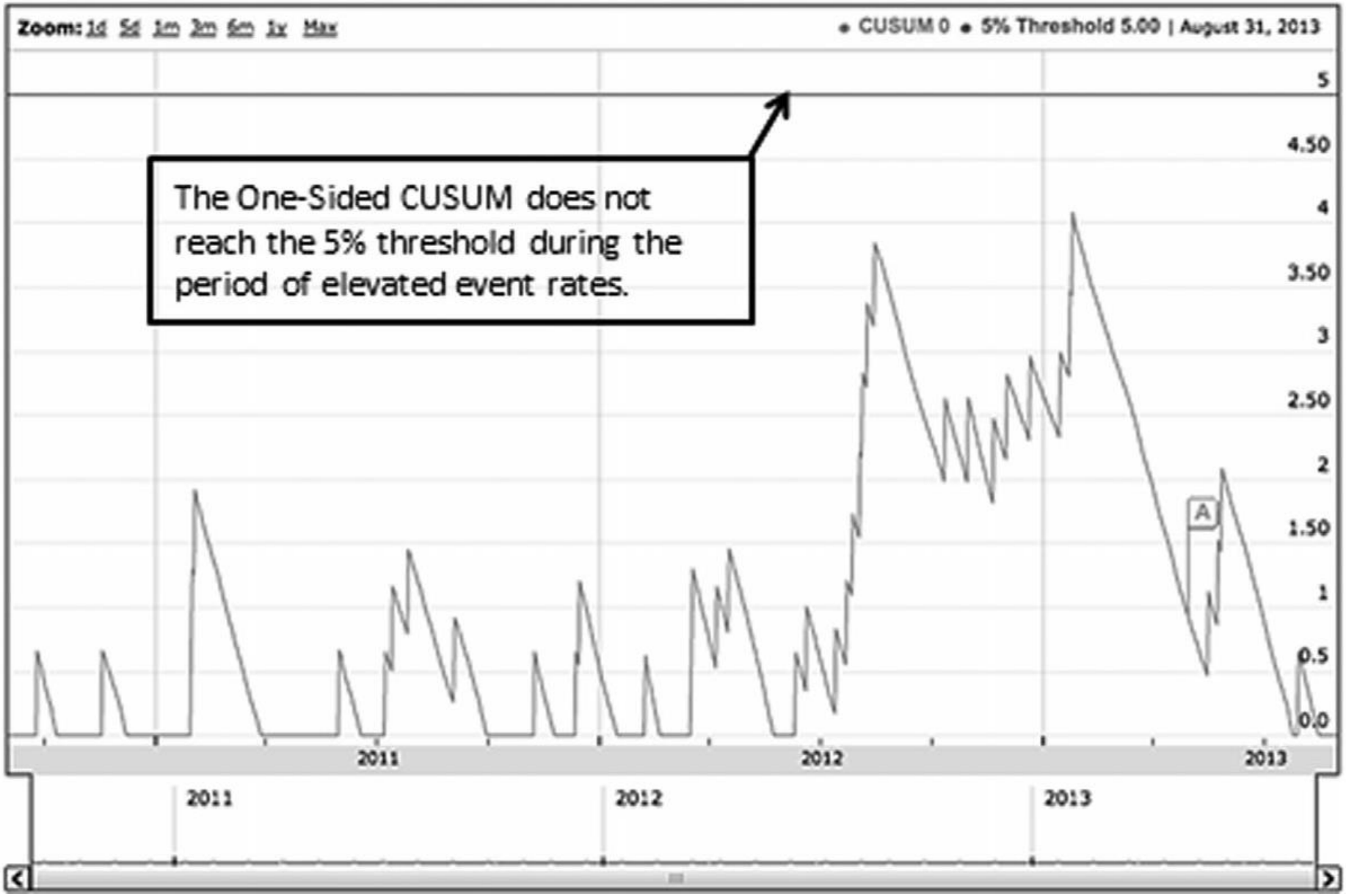
- Cohort used in the reports is 2.5 years.
  - Always hoping for improved results.
- Need faster method to see effect of QI processes.

# CUSUM Charts

- Graphical representation of outcomes for process
  - Can be risk-adjusted charts for important donor and recipient characteristics
- Plot outcomes over time to compare the results with expected outcomes based on a national model of mortality or graph failure
  - 2 types: O - E charts and One-sided charts
- Trends in the plot line suggest improving or declining outcomes
  - Once the trend line reaches a certain predefined level (one-sided charts) or exceeds a certain slope (O - E charts) the CUSUM signals


OBSERVED - EXPECTED CUSUM: DECEASED DONOR ADULT ONE-YEAR GRAFT SURVIVAL
Zoom: 1d 5d 1m 3m 6m 1y Max
A period of lower than expected event rates.
A period of higher than expected event rates.
2011
2012
2013

# One-Sided CUSUM: Deceased Donor Adult One-Year Graft Survival



# CUSUM Conclusion

- CUSUM charting provides a reliable, risk adjusted method of tracking outcomes of a clinical process
  - Graphical output is easily interpretable with a minimal amount of training
  - Providing outcomes are promptly reported the CUSUM can provide real time insight into TC outcomes

# Do PSRs Effect Center Behavior

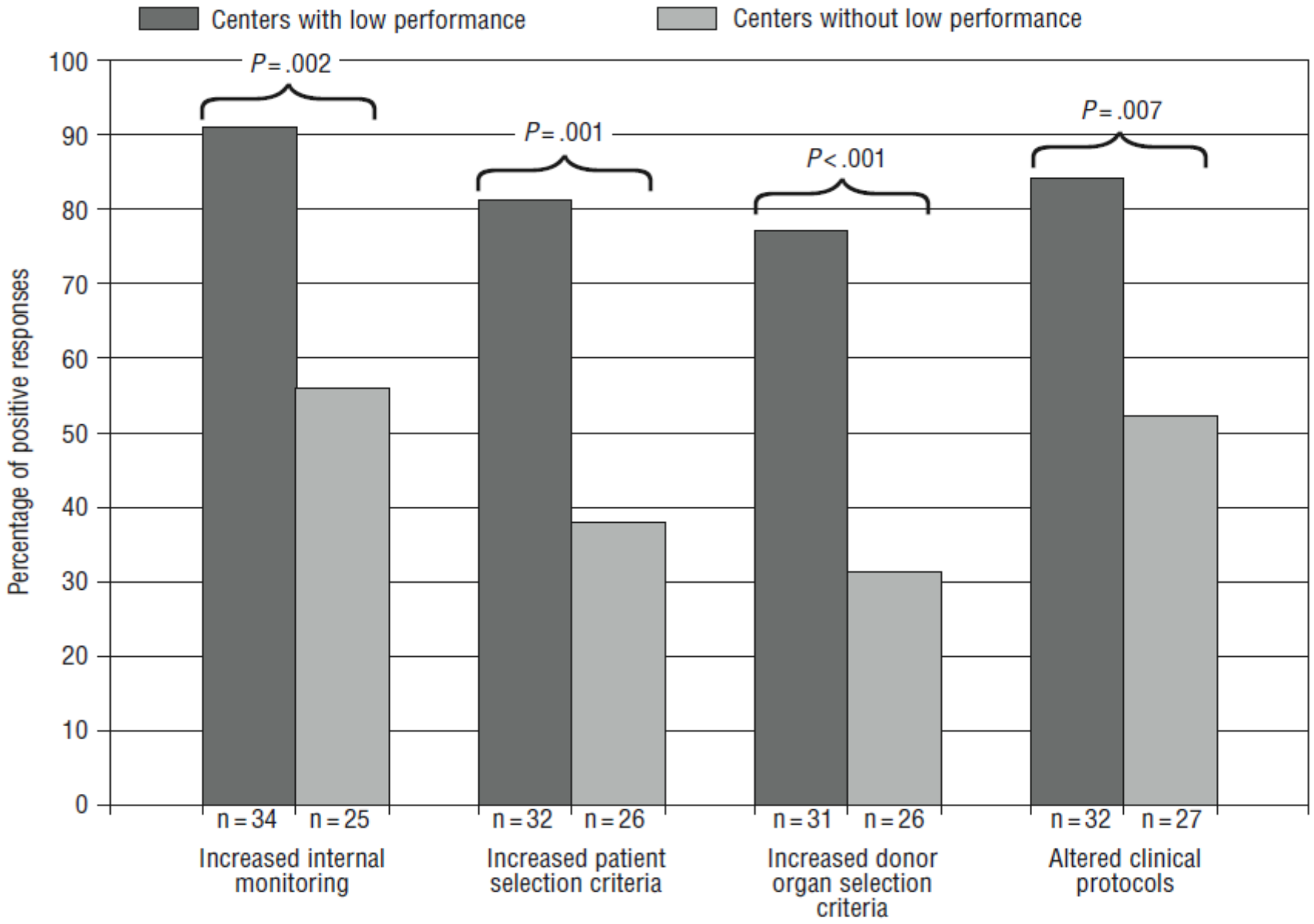



Figure 2 Reported changes in practice associated with incidence of low performance assessments. (Missing reponses excluded from proportions.)

Schold, J Progress Transpl 2010

# Can You Limit Your Risk?

- Does your center do better or worse with a given category that is adjusted e.g. DCD donors?

# High-risk Transplants

## Donor Factors: How They Are Accounted For

- DCD: adjusted
- Older donors: age adjusted
- Creatinine: adjusted
- Donor Biopsy: Not Adjusted

Garonzik-Wang JM, Segev DL. *Am J Transplant*. In press.

# Limit Risk?

- Because of the adjustment, excluding DCD donors may not improve the outcome and will decrease the number or transplants.
- Choosing donors on basis of biopsy may limit risk.

1. Dickinson DM, et al. *Am J Transplant*. 2008;8(Pt 2):1012-1026. (B)

# Many things are not "adjusted" for:

- Cardiovascular disease
- Nutritional status
- Income
- Education
- Patient support networks
- Donor Biopsy
- Noncompliance
- Prior malignancies
- Ancillary quality of care
- Smoking status
- Employment status
- Other comorbidites
- Drug use
- Psychological conditions
- Genetics

# Adjustments

- Things that are captured but not perfectly
  - Diabetes will be a problem only if your patients (or donors) have more severe diabetes or longer history of diabetes than other centers' patients (or donors)
  - DCD will be a problem only if you use DCDs with much longer warm time, for example, than other centers
  - Cholangiocarcinoma adjusted for but HCC outside of Milan not adjusted

# High Risk Transplant

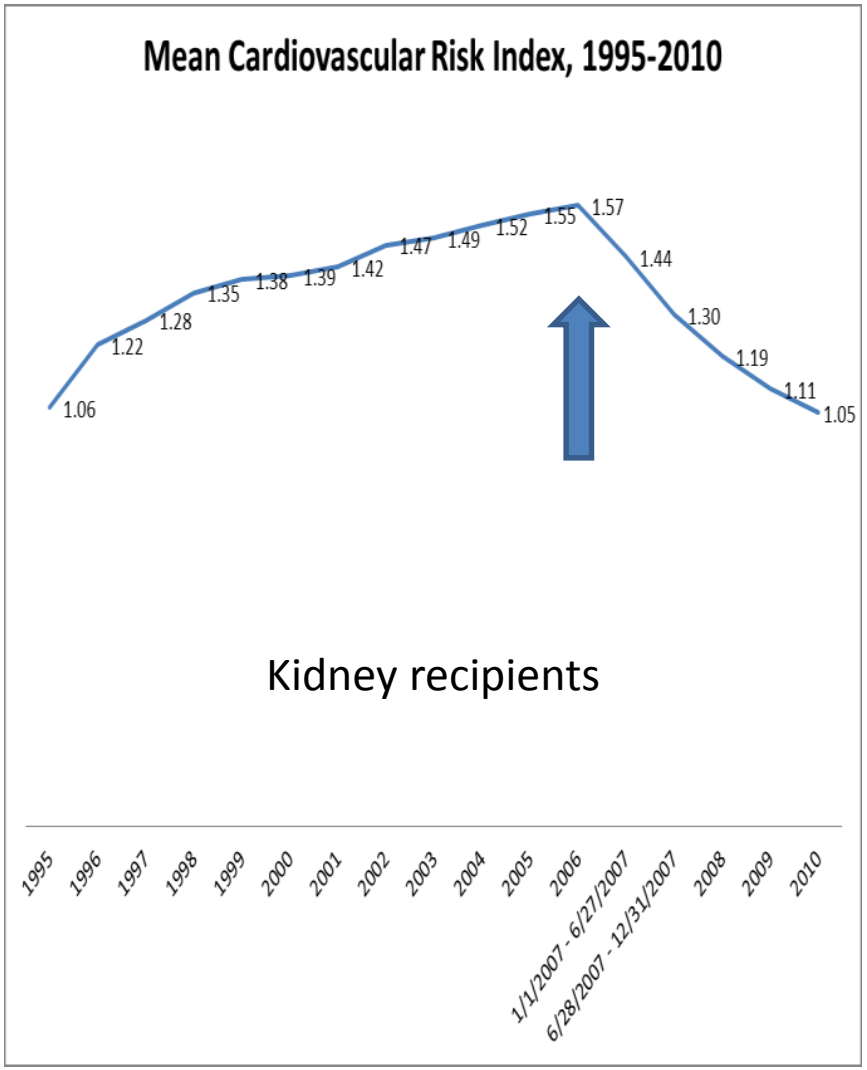
- Unadjusted (usually uncaptured) factors that are more prevalent in your patients than at other centers
  - Desensitization
  - Cardiovascular disease
  - Re-re-transplantation
  - Organs that “seem” OK by captured factors but have bad biopsies

# Center Risk Aversion

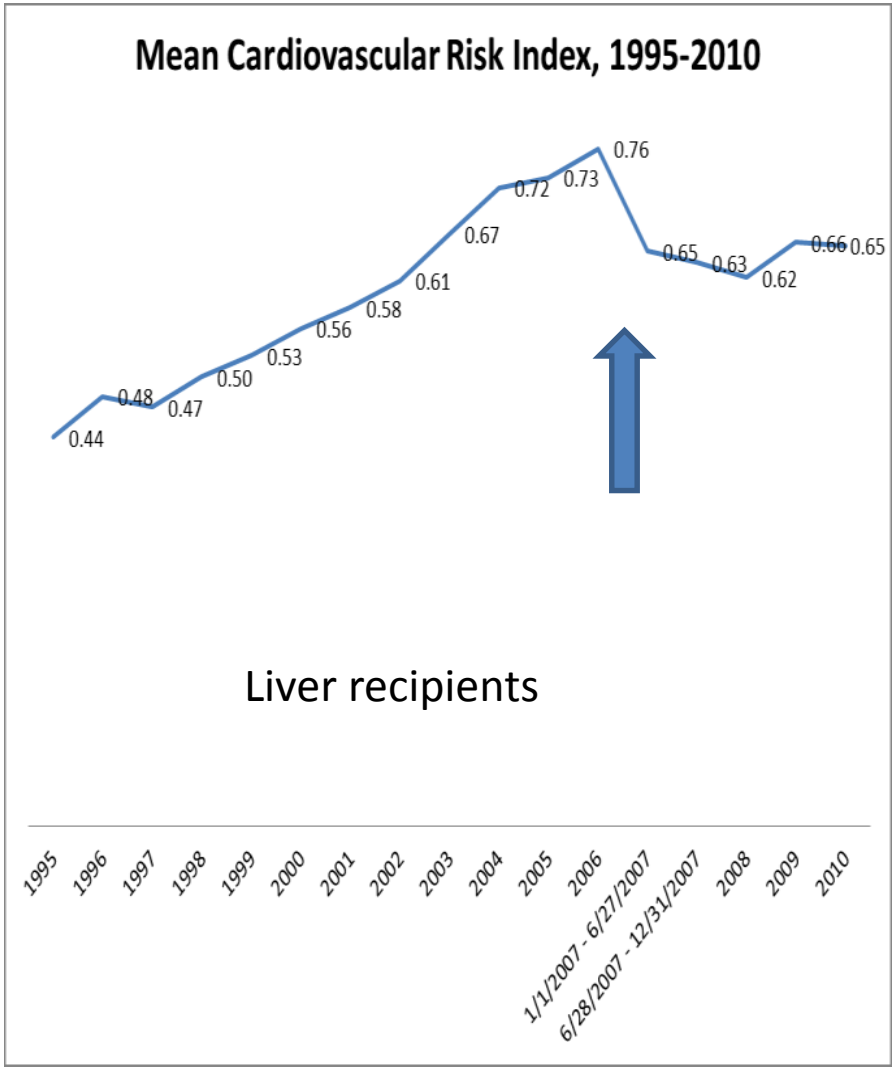
- SRTR Risk-adjustment is known to inadequately adjust for cardiovascular risk.
- Have centers responded to CMS rules by not transplanting patients with CV risks, who previously would have been transplanted?

- Abecassis PSR Consensus Conference 2012

# Effect of CMS Conditions of Participation




Kidney recipients




Liver recipients

Wang, et al. Oral Presentation AASLD 2011.

# How Should Your Center Face Regulation?

- Easier way vs. harder way
- Easy way will keep your center out of CMS/OPTN jail
- Easy way will improve your center's care of patients
- Swallow the Kool-Aid and reach acceptance

# Kubler-Ross

- The stages, popularly known by the acronym **DABDA**, include:
- **Denial** —"This can't be happening“
- **Anger** — "Why me? It's not fair!"; "How can this happen to me?"; '"Who is to blame?“
- **Bargaining** — "I'll do anything so I won’t have to do it."
- **Depression** — "I'm so sad, why bother with anything?";
  **Acceptance** — "It's going to be okay."; "I can't fight it, I may as well prepare for it."

# How to Use K-R

- Recognize that anything new will create anxiety
- K-R is how people deal with new anxiety producing events
- Leader needs to decide whether any of the earlier stages are likely to be productive
- If end is inevitable then leader needs to recognize this and move forward

# Common Anxiety Provoking Events

- 80 hour work week
- Electronic Medical Record
- Physician must cover their salary

# Leadership and Kubler-Ross

- Leader has the vision to recognize the inevitable: Acceptance
- Leader's job is to get team through the Kubler-Ross stages: Denial, Anger, Bargaining, and Depression
- Once Acceptance has been reached then work toward goal can be effective

# Two-Pronged Approach?

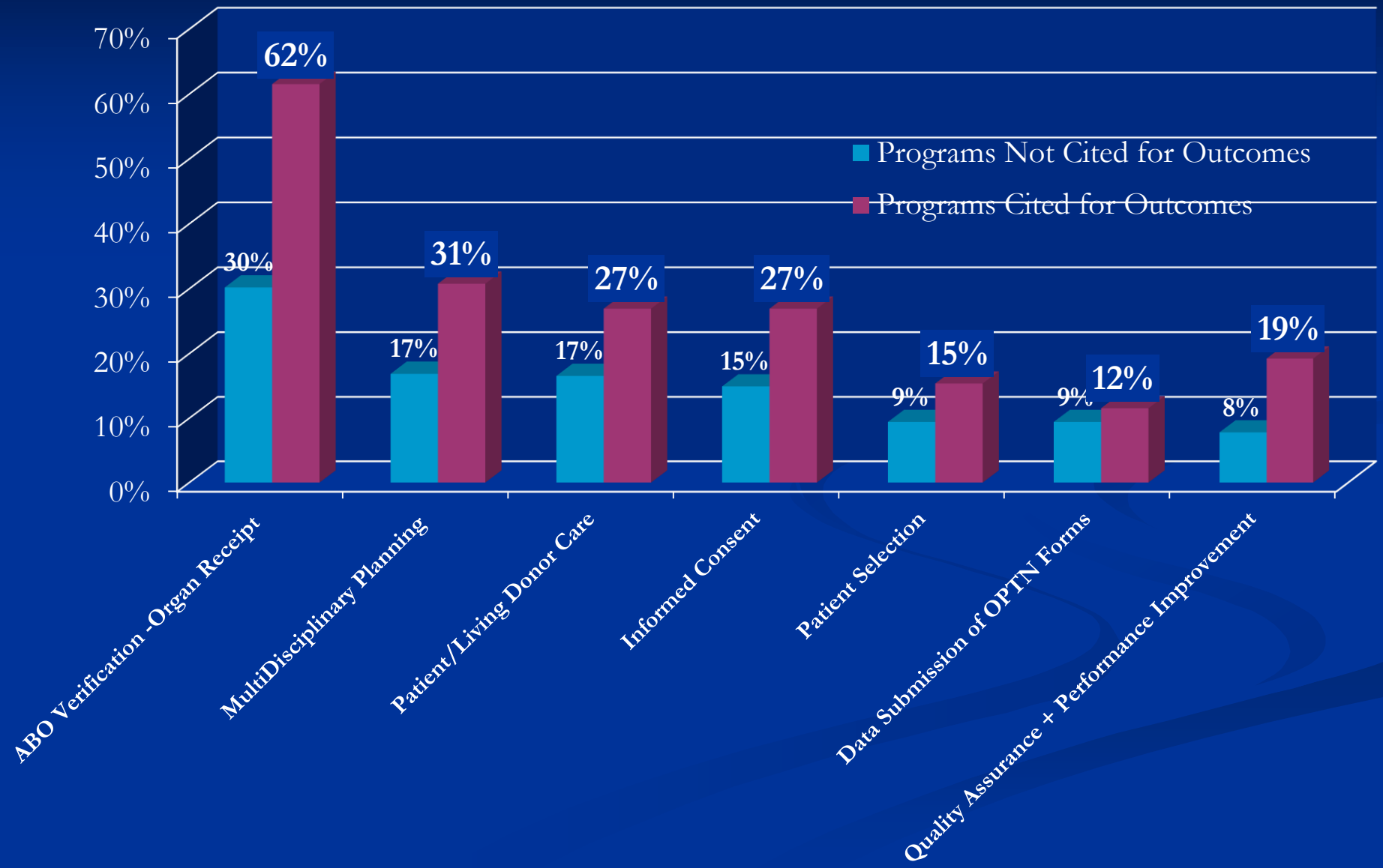
- Leader may/can be  involved with higher level interactions with regulation
  - ASTS/AST/AOPO
  - Transplant center administration
- Need to separate what actions maybe taken at higher level about the regulation from getting implementation happening locally
  - Time frame, chance of successful change, ..
- Waiting for a savior who may never come can delay acceptance

# Kool-Aid

- Goal is to improve patient care
- Agreement that CMS/OPTN regulations are intended to improve patient care
- Developing processes to meet regulations will improve patient care

# Types of Program Deficiencies N=334

## (Programs w/ Poor Outcomes v All Others, 26 v. 308)



# How To

- Need right people on board
  - Those who have reached acceptance
    - “It is what it is..”
  - Isolate/insulate the believers from those depressed, angry people in denial who want to bargain
  - Keep process moving forward while others join.

# How to Make the Movement Successful

- Get resources
- Design process
- Develop Policy
- Monitor and audit
- Maintenance

# Get Resources

- Healthcare organizations understand the words “Center for Medicare and Medicaid Services”
- If the organization wants successful transplant program and avoid CMS deficiencies they will provide resources
- If you can’t get resources figure out whether the organization doesn’t care or is in some K-R stage
- Use near-misses and misses as driver to raise awareness

# Resources

- Transplant center administrator
- Process designer and implementer
- Outcomes monitor
- Physician champion (First Follower?)
- Carrot and stick person
  - Probably you

# Process Design and Implementation

- Rule 1: Keep it simple
- Use as many IT tools as possible in the process without violating rule 1
  - Easier monitoring
    - Paper is a problem
  - Easier to change?
- Make it bomb-proof but simple

# Policies And Procedures

- Policies and procedures
  - Important to have policies and procedures that cover specific items in the regulations.
  - Important to follow your own policies and procedures
  - May not want to be too specific as you can be held to the policies
  - Policies need to be reviewed and updated on a regular basis

# Is Process Working?

- Need audits
- Audits should examine key steps
- Goal of compliance
- Frequent monitoring until compliance goal then less frequent

# Maintenance

- Design in successful maintenance
  - Need to involve those involved with maintenance early
  - Designers and Implementers may not be maintenance people
  - Need involvement of maintenance folks in design for pride of ownership

# Maintenance

- Need to have periodic review
  - Need to keep the weeds out
- Run fire drills
  - Make sure you can demonstrate compliance
- Maintenance folks should do this.
- Trust but verify

# Overall

- Like a garden
  - Planning
  - Building
  - Testing
  - Maintenance

# Final Goal

- Get acceptance from all involved
  - Those involved realize inevitability
    - May have to get rid or marginalize those who get stuck in earlier stage.
  - Next anxiety producing event will have shorter stages to goal
  - Others will want to be leader or first follower.

# Thanks

- Dorry Segev
  - Provided slides effect of CMS on centers
- David Axelrod
  - Provided CUSUM Slides
- Tom Hamilton
  - CMS slides
- Kim Olthoff
  - Charts