

Medicare National Survey & Certification Program
for
Solid Organ Transplant Programs

Advisory Committee on Organ Transplantation

March 12-13, 2014

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Survey & Certification Group
Centers for Medicare and Medicaid Certification

Plan for the Discussion

1. *CMS Regulation*

2. *Transplant Center Responses*

Overview of CMS Approach

Outcomes Expectations

- CMS National Coverage Decisions (NCDs)
 - Heart – **1986** – *if* meeting Survival Minimum (1-Yr 73%, 2-Yr 65%)
 - Liver – **1991** - *if* meeting Survival Minimum (1-Yr 77%, 2-Yr 60%)
 - Lung – **1995** - *if* meeting Survival Minimum (1-Yr 69%, 2-Yr 62%)

CMS Requirements + Survey Findings

■ Program Design + Management

- ABO Verification
- **Multi-Disciplinary Planning**
- **Patient + Living Donor Care**
- Informed Consent
- **Patient Selection**
- Data Submission to OPTN
- **Quality Assessment + Performance Improvement (QAPI)**

■ Risk-Adjusted Outcomes (Graft + Patient Survival)

Deficiency is Cited if:

1. SMR: Observed/Expected Failures > 1.5 (One-Year Post-Tx)
2. $P < .05$ (one-sided value, same as OPTN)
3. Observed minus Expected > 3

CMS + OPTN Outcome Measures

CMS	OPTN
<p data-bbox="69 315 919 365"><u>Statistical Measure for Outcomes</u></p> <p data-bbox="204 372 707 422"><i>(Graft + Patient Survival)</i></p> <p data-bbox="287 429 697 472">If <u>All 3 Below Apply</u>:</p> <ol data-bbox="46 529 929 772" style="list-style-type: none">1. SMR: Observed/Expected Failures > 1.5 (One-Year Post-Tx)2. P < .05 (one-sided value, same as OPTN)3. Observed minus Expected > 3	<p data-bbox="1035 315 1808 365"><u>Statistical Measure for Outcomes</u></p> <ol data-bbox="973 522 1866 722" style="list-style-type: none">1. Probability is +75% that HR Exceeds 1.2<p data-bbox="1161 579 1209 615"><u>or</u></p>2. Probability is +10% that HR Exceeds 2.5 (small volume programs)
<p data-bbox="108 1046 880 1089"><u>Condition-Level Deficiency is Cited if:</u></p> <ul data-bbox="46 1096 929 1289" style="list-style-type: none">• 2 of the most recent 5 SRTR reports indicate that all 3 of the above thresholds are crossed (i.e., the most recent SRTR report plus 1 other report).	<p data-bbox="1209 1046 1634 1089"><u>Identified for Review</u></p> <ul data-bbox="973 1096 1837 1189" style="list-style-type: none">• 1 SRTR report indicates that the above applies

Plan for FY 2015-2016

- Calculate Both Measures for Each Program
- Compare Effect of the 2 Measures
- Determine in FY2016 How to Best Restore Alignment of Measures
- In the Meantime:
 - Review Results of OPTN's Measure if a Program is Cited by CMS but not Flagged under the OPTN Measure
 - Include this review in Mitigating Factors Consideration

Public Policy Challenge ...

1. How might CMS best back up OPTN?
2. How might CMS reinforce the tradition of continuous quality improvement of the transplant community?

Public Policy Challenge ...

1. How might CMS best back up OPTN?
2. How might CMS reinforce the tradition of continuous quality improvement of the transplant community?
 - Require Internal Quality Improvement = QAPI
 - Mitigating Factors Process
 - System Improvement Agreements

Patient & Graft Survival

- **Single SRTR Rpt = Flag** = 8-11% of Programs
- **Condition-Level Citation** = 3 - 5% of Programs
 - 2 of 5 SRTR Rpts w/Statistically Significant Outcomes
(Most Recent + 1 Other of 5 SRTR Reports)
- **Mitigating Factors Process**
 - Up to 210 Days
 - Allows for 3d SRTR Rpt
 - Allows Time for Additional Improvements
- **SIA** – if Progress + Hospital Commitment

Mitigating Factors Provision

- CMS Regulations - Permit Consideration of “Mitigating Factors”
- Main Types of Mitigating Factors
 - Natural Disasters (e.g. Hurricane)
 - **Innovation (high HLA population, etc.)**
 - **Improvement**
 - Robust Program Improvement
 - Evidence of Improved Outcomes
- Programs submit request for consideration to CMS Central Office (to ensure national consistency)

New - Expanded MF Factors Regulation

42 CFR 488.61(f-h)

ecfr.gov (browse to Title 42, click on 482-699,
click on 488, click on 488.61)

Adds

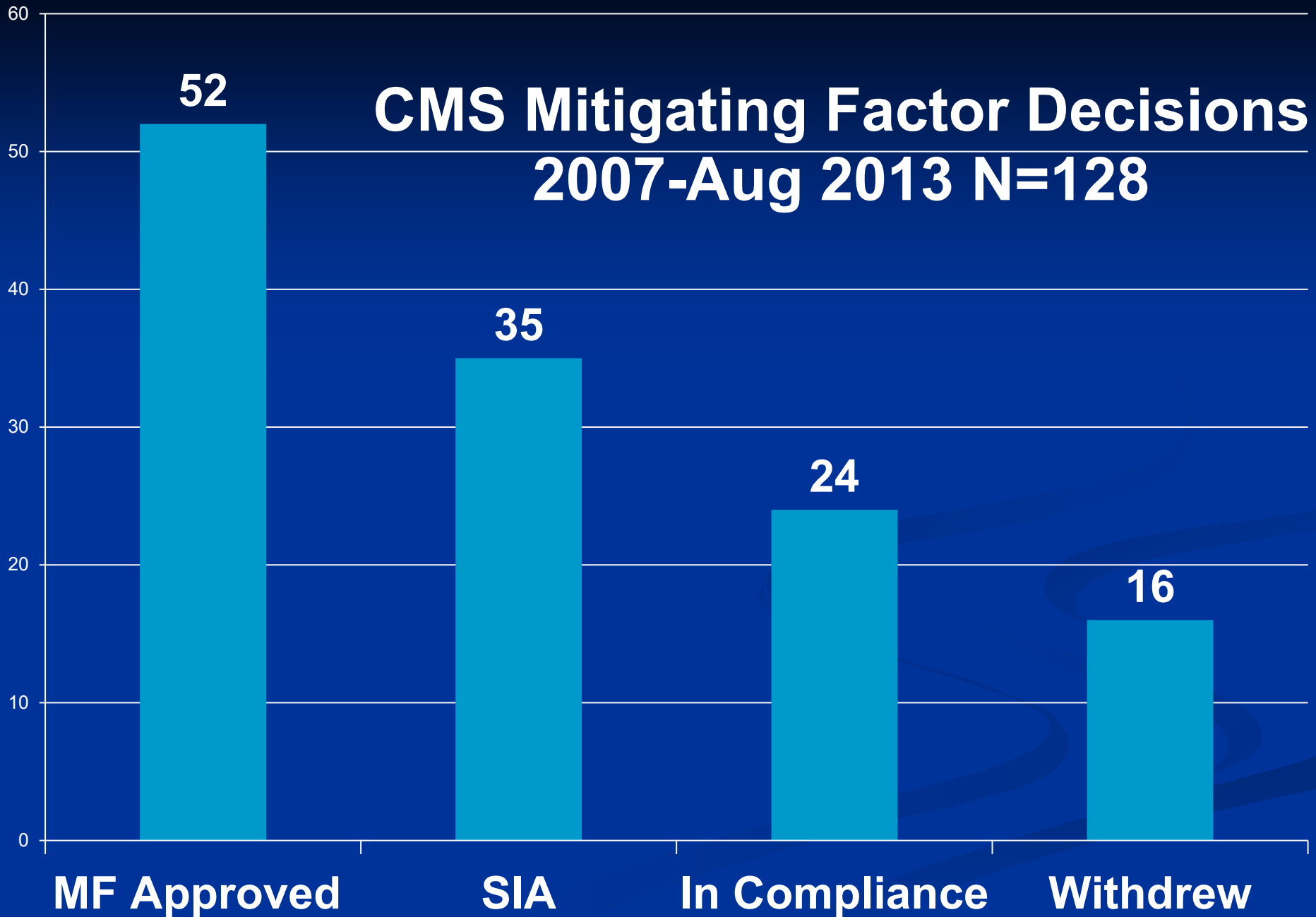
- Explicit Recognition for Program Improvement as a Mitigating Factor
- Innovation as a Factor
- Systems Improvement Agreement Transparency

Favorable MF Decisions for Outcomes

Five Elements – All Fulfilled

1. Program Improvements
2. Substantial
3. Address Root Causes
4. Implemented, Institutionalized, Sustainable
(not just plans)
5. Evidence (Data) of Improved Outcomes to
Support a Finding of Present-Day Compliance

CMS Mitigating Factor Decisions 2007-Aug 2013 N=128



System Improvement Agreements (SIAs)

■ Key Elements of SIA

1. Peer Review: Onsite Peer Review with Topic Areas Specified by CMS
2. Quality Consultation: Onsite Quality Consultant
3. QI Investments: Further Quality Improvement Efforts by Hospital
4. QAPI System Improvements: including better use of SRTR Data
5. Waitlist Assistance: Assistance to People on Waitlist (if Transferring)
6. Reporting: Regular Data & Program Reporting to CMS
7. Appeal: Waiver of Appeal Rights
8. After Action Report

■ Extension of Dates: CMS Extends the Effective Date of Medicare Termination during the SIA

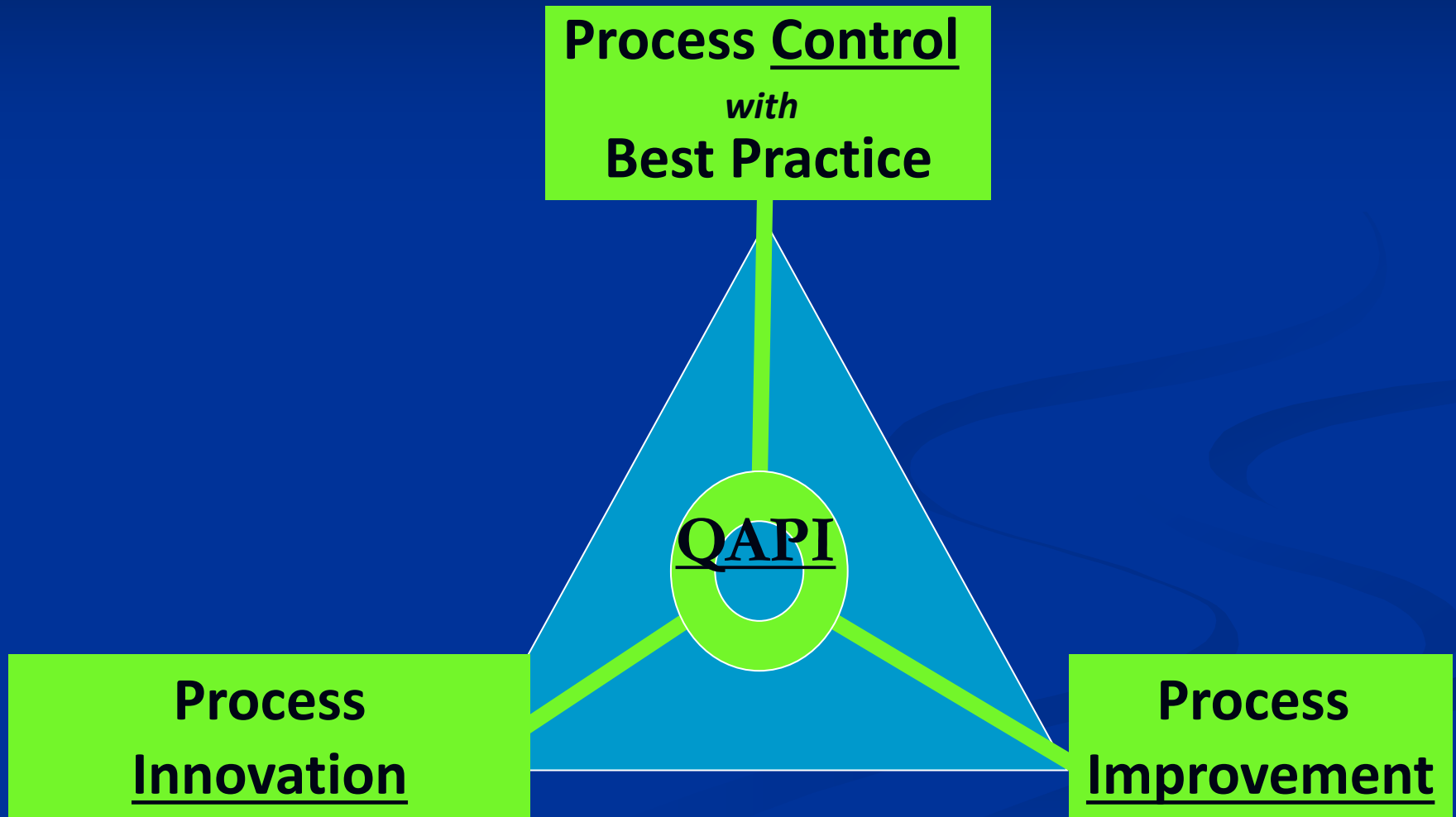
■ Offered Only in Promising Circumstances, and if Strong Institutional Support is Evident

QAPI “Motto”

If We Lose the Patient ...

...We Don't Lose the
Lesson

Broad Challenges for Transplant Centers



Five Medicare QAPI Themes

and

Examples of Transplant Center Actions



5

QAPI Theme: Five Major Aspects

1. Design + Scope

2. Feedback, QI Systems, Awareness

(a) Adverse Events

1. Reported,
2. Tracked,
3. Investigated
4. Analyzed + Used

(b) Quality Indicators

1. Problem Prone Areas
2. High Risk Areas
3. Tracked
4. Used for Quality Improvement

3. Performance Improvement Processes

4. Systemic Improvement

5. Governing Body + Leadership

Adverse Events

1. Reported (e.g., incident reporting systems)

Special Challenges for
Post-Transplant Care

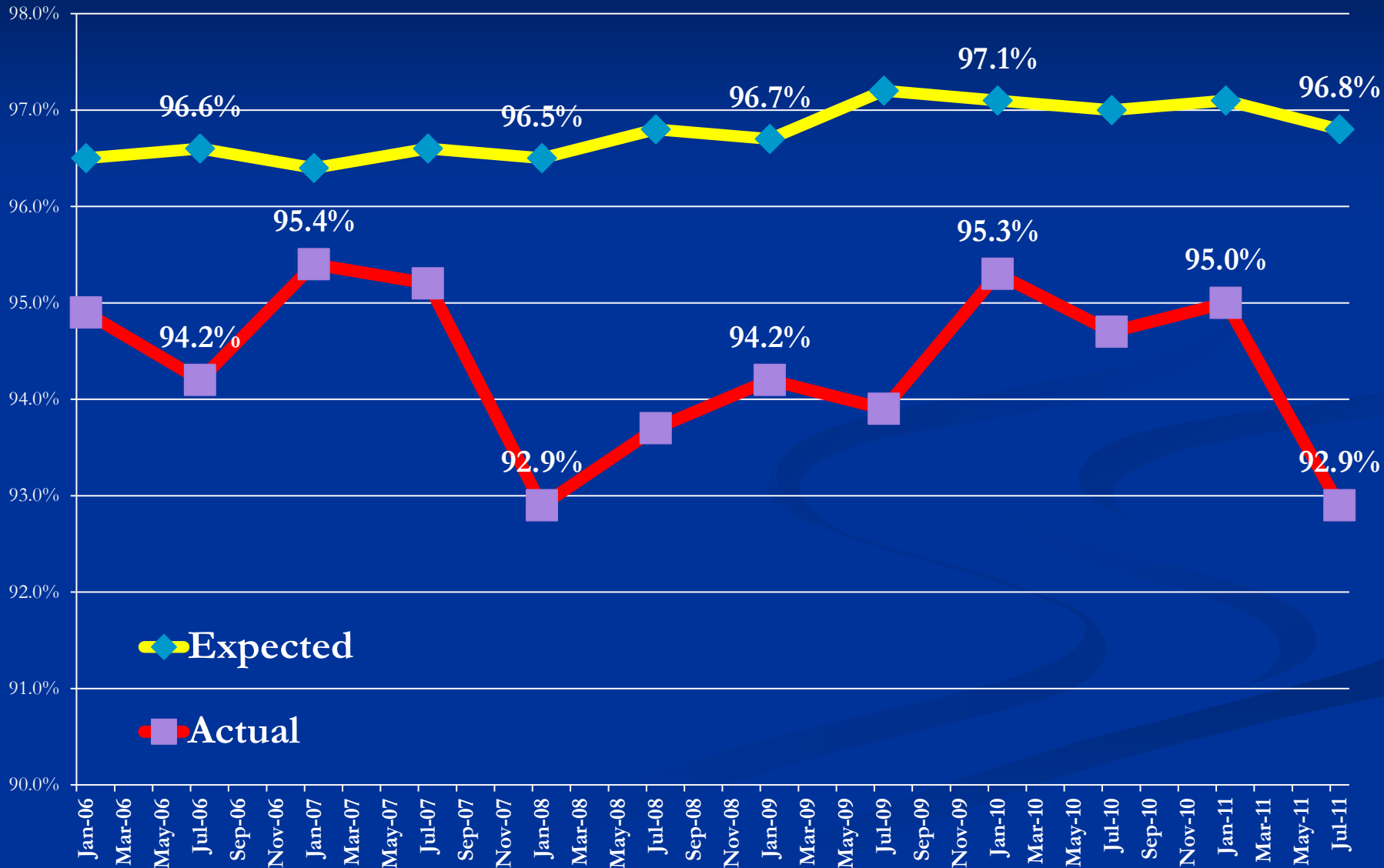
2. Tracked,
3. Investigated
4. Analyzed
5. Used ...“to effect changes in the transplant center’s policies and practices to prevent repeat incidents (42 CFR 482.96(b)(2))

Turnaround Actions by Transplant Programs - Examples

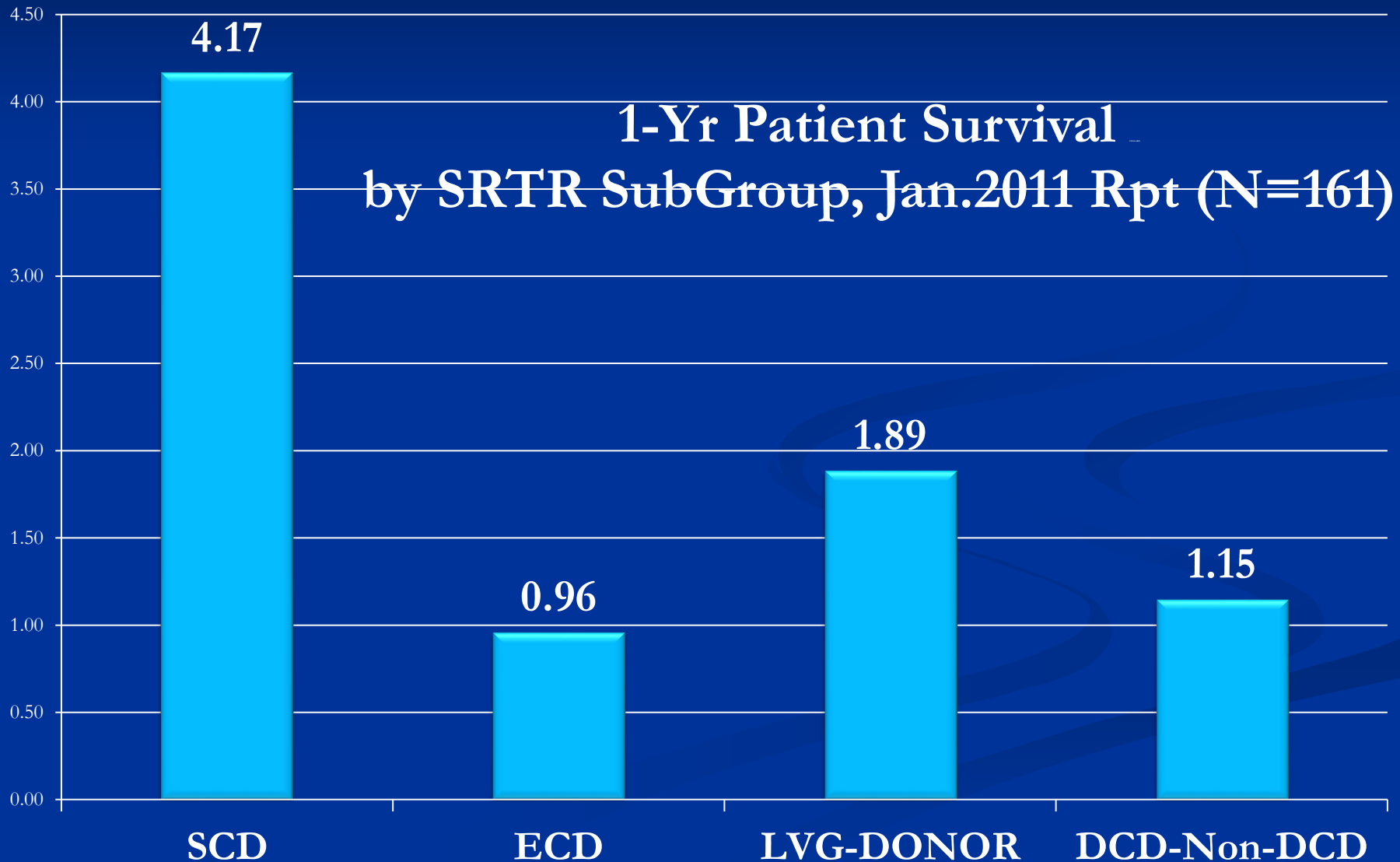
1. Challenge the Barrier of Beliefs

Case Example # 1 - One-Year Patient Survival

Adult Kidney Program

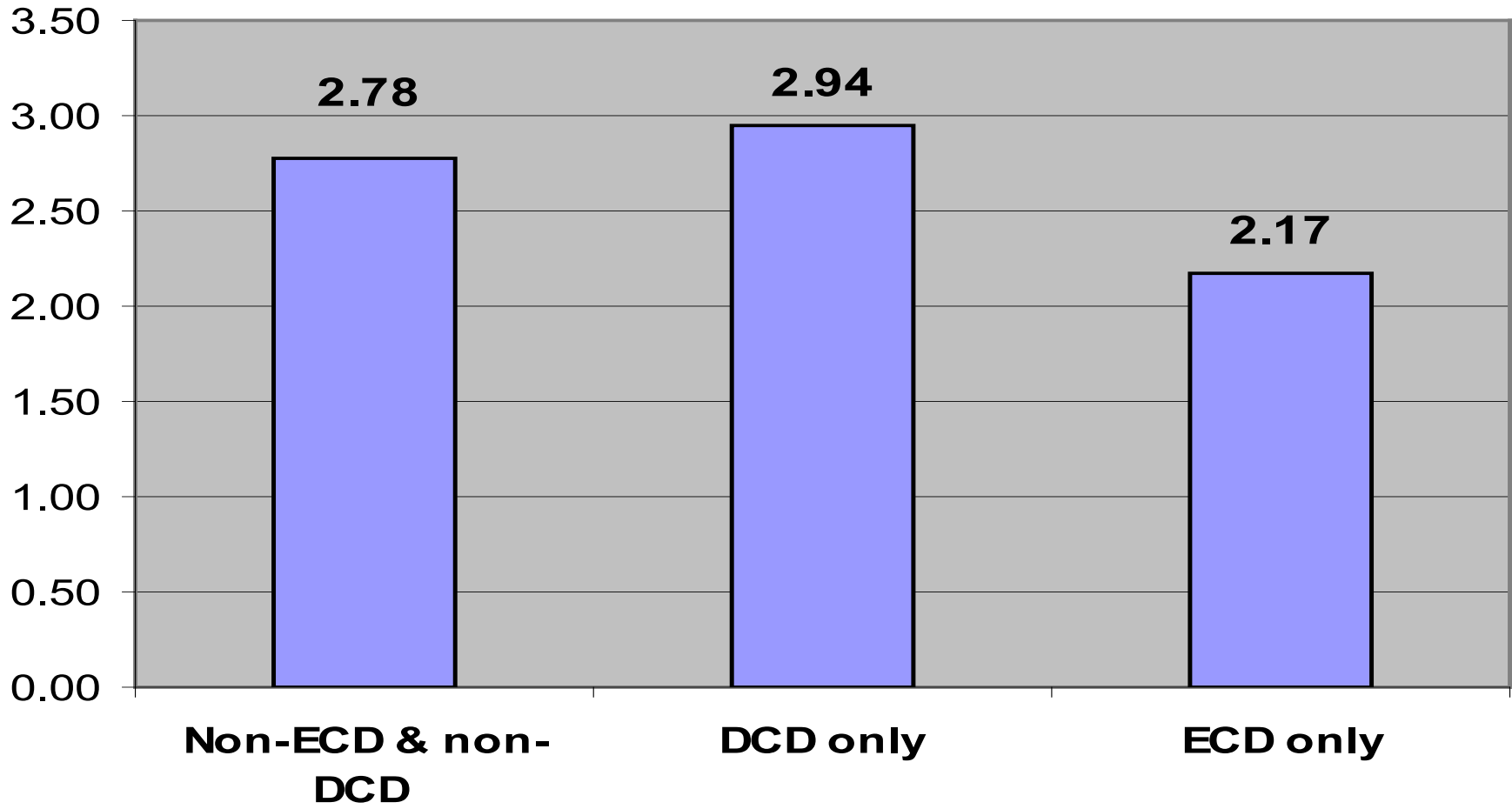


Case Example #1 *continued* – Adult Kidney Standardized Mortality Ratio (SMR)



Case Example # 2 – Liver Program Unacquainted with its Data

**Case Example - Standardized Patient Mortality Ratio -
Adult Liver - 1/2006-12/2007 - (N=35)**

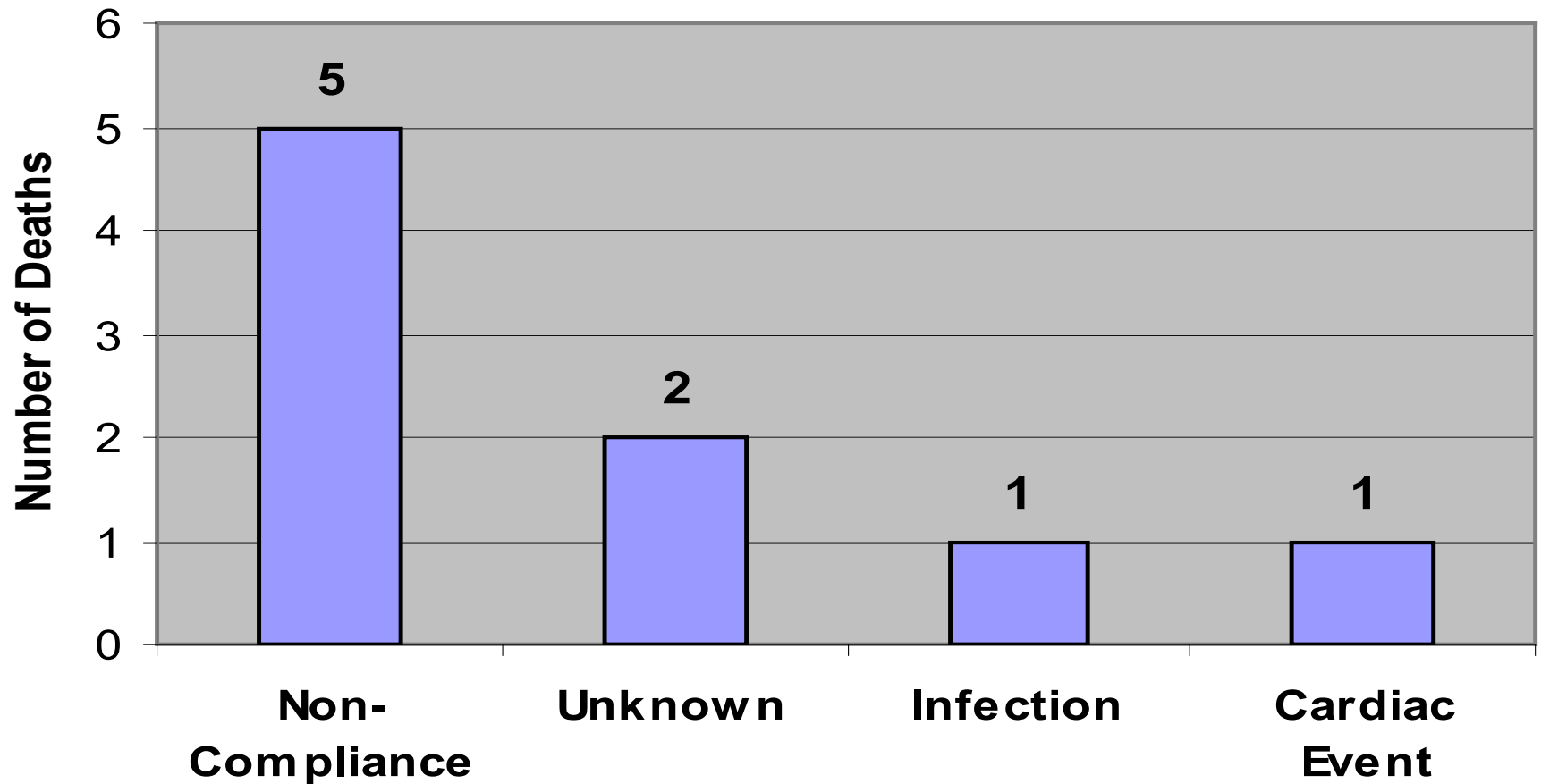


Turnaround Actions by Transplant Programs

1. Challenge the Barriers of Beliefs
2. Improve Root Cause Analyses and QAPI

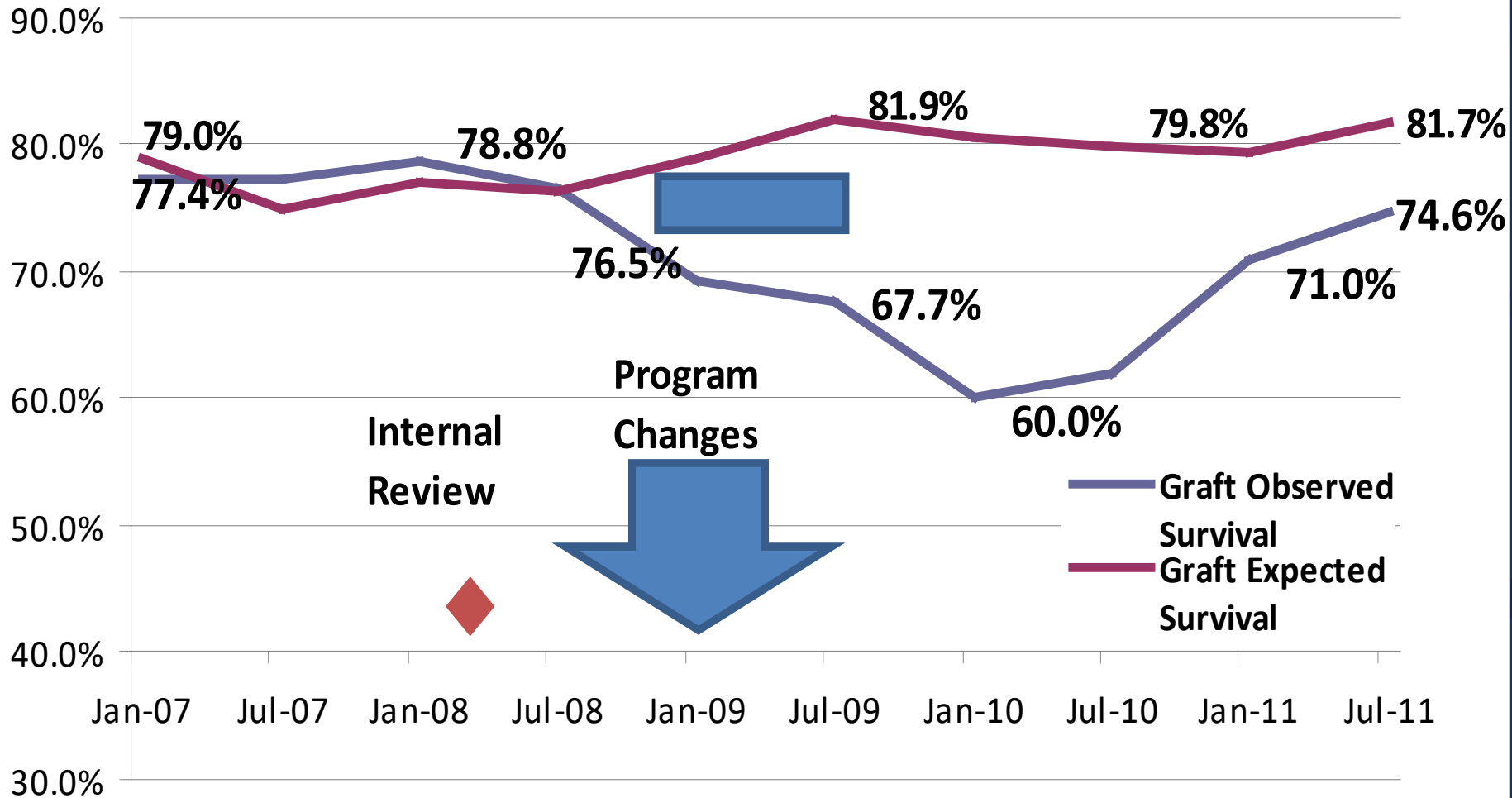
Case Example #3 – Root Cause Analysis Challenge

Case Study: Reported Initial Analysis of Patient Deaths



Case Example # 4 : Lung Program on Top of Its Data

Adult Lung Graft SMR - by SRTR Rpt Date CACSa



Turnaround Actions by Transplant Programs

1. Challenge the Barriers of Beliefs
2. Improve Root Cause Analyses and QAPI
3. Improve Hospital Alignment
 - Invest in Staff
 - Electronic Health Records
 - ICU Coordination & Training
 - Specialize the Specialists

Example - Multi-Disciplinary Teaming & Specializing the Specialists

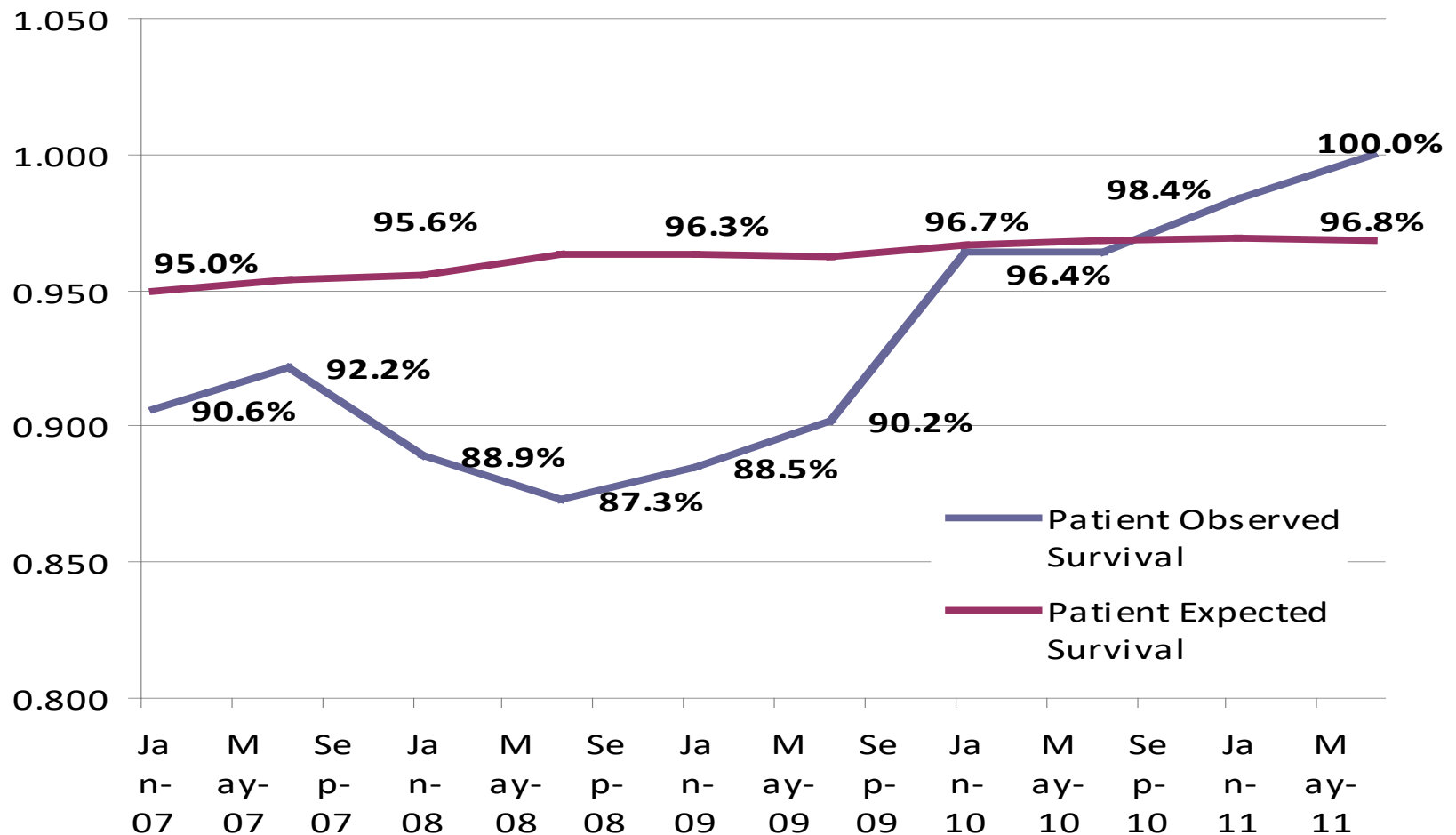
A. Role of Cardiology

- Improved Cardiac Evaluation Pre-Op
- Improved Pre-Op Intervention (e.g., Stents before Transplant rather than After)
- Dedicated Specialists

Research: Cardiovascular events are the leading cause of deaths in patients with ESRD.

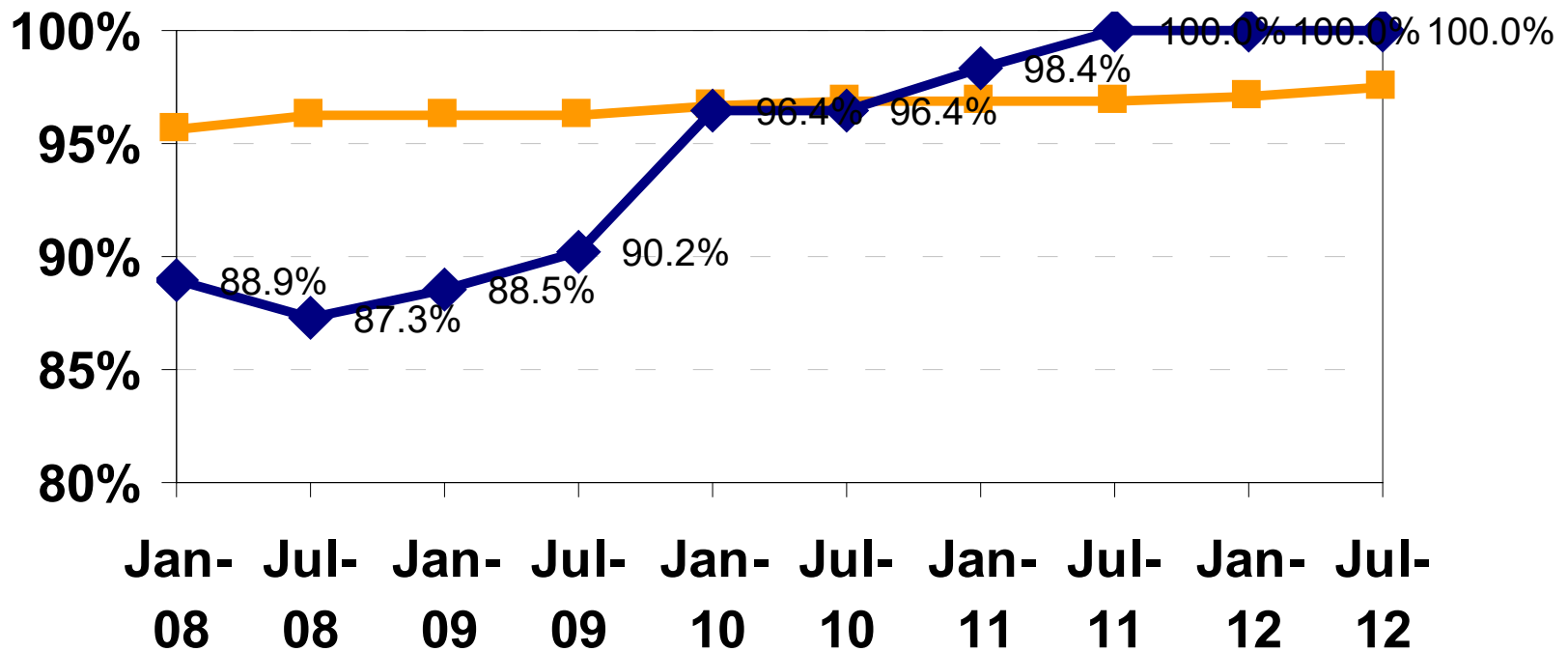
Case Example # 5 – Impact of Cardiology Improvement – Pre + Post Tx

Patient Survival by SRTR Rpt Date - Adult Kidney Program - 2007-11



Case #5 - Patient Survival –Adult Kidney Program Updated to 2012

1-Year Patient Survival



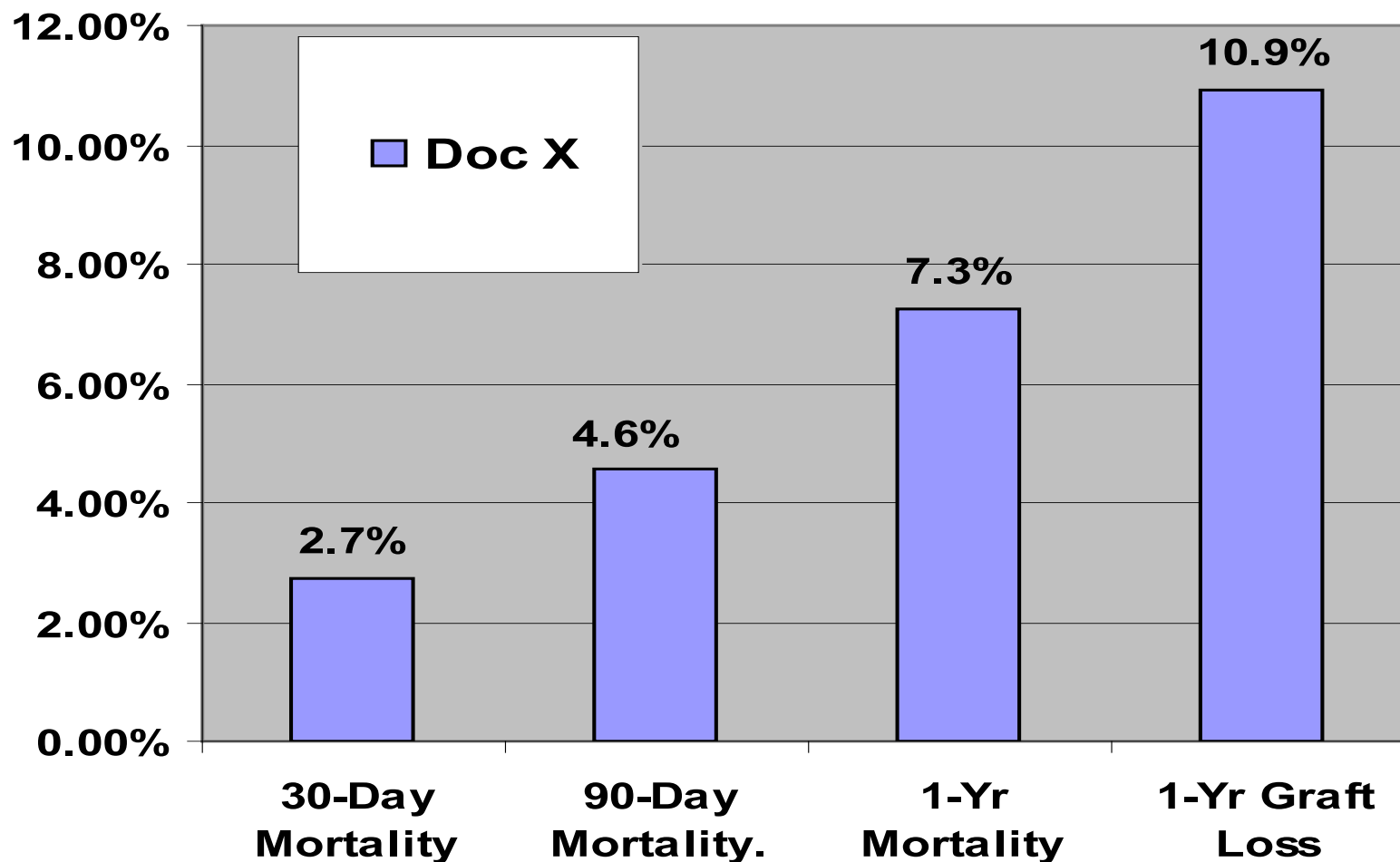
—■— Expected Patient Survival
—◆— Actual Patient Survival

Turnaround Actions by Transplant Programs

1. Challenge the Barriers of Beliefs
2. Improve Root Cause Analyses and QAPI
3. Improve Hospital Alignment
4. Address Personnel Issues

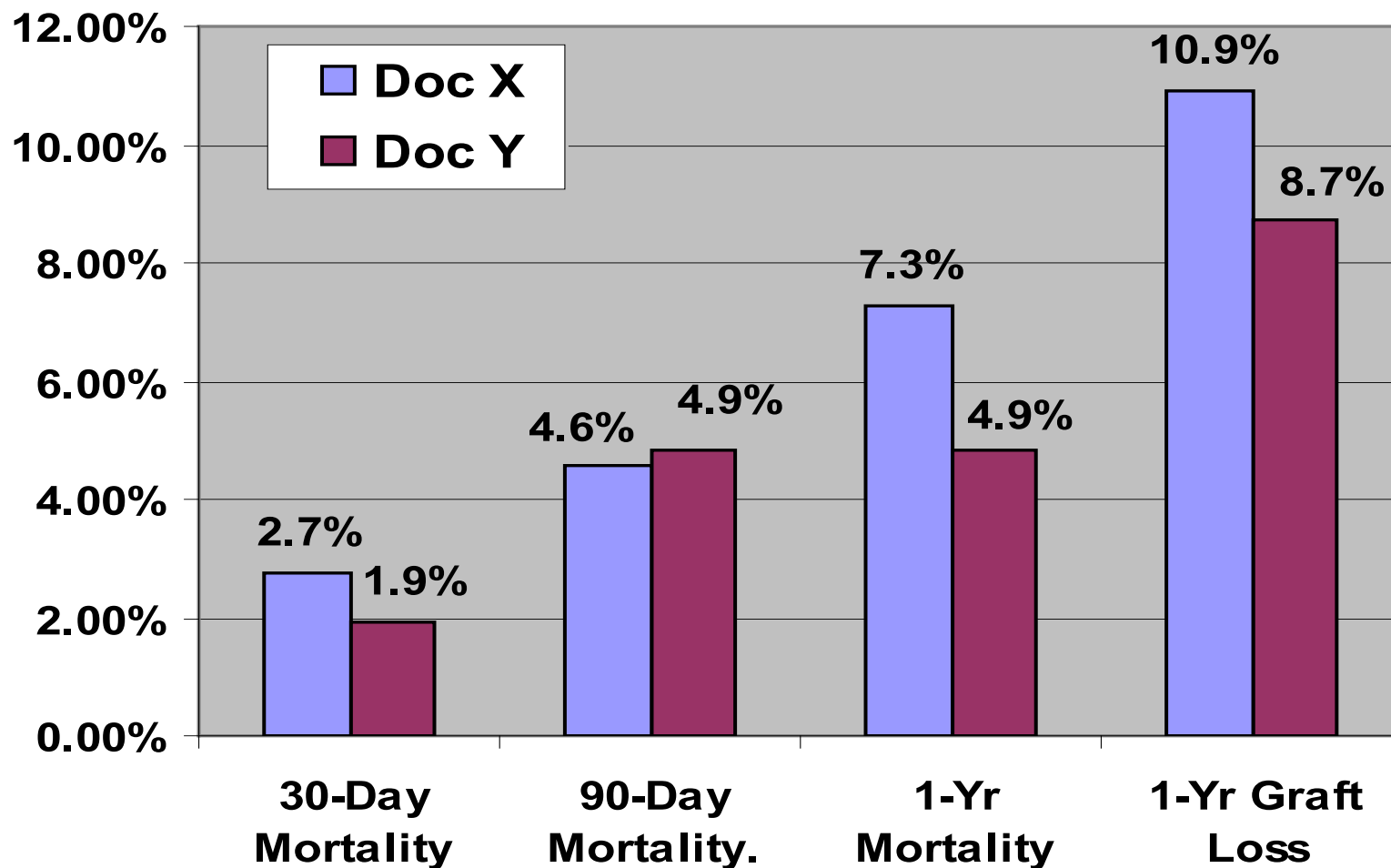
Case Example # 6: Using SRTR Data to Improve the Program

**Mortality Rate by Surgeon - Adult Kidney Program -
Jan. 2010 SRTR Data**



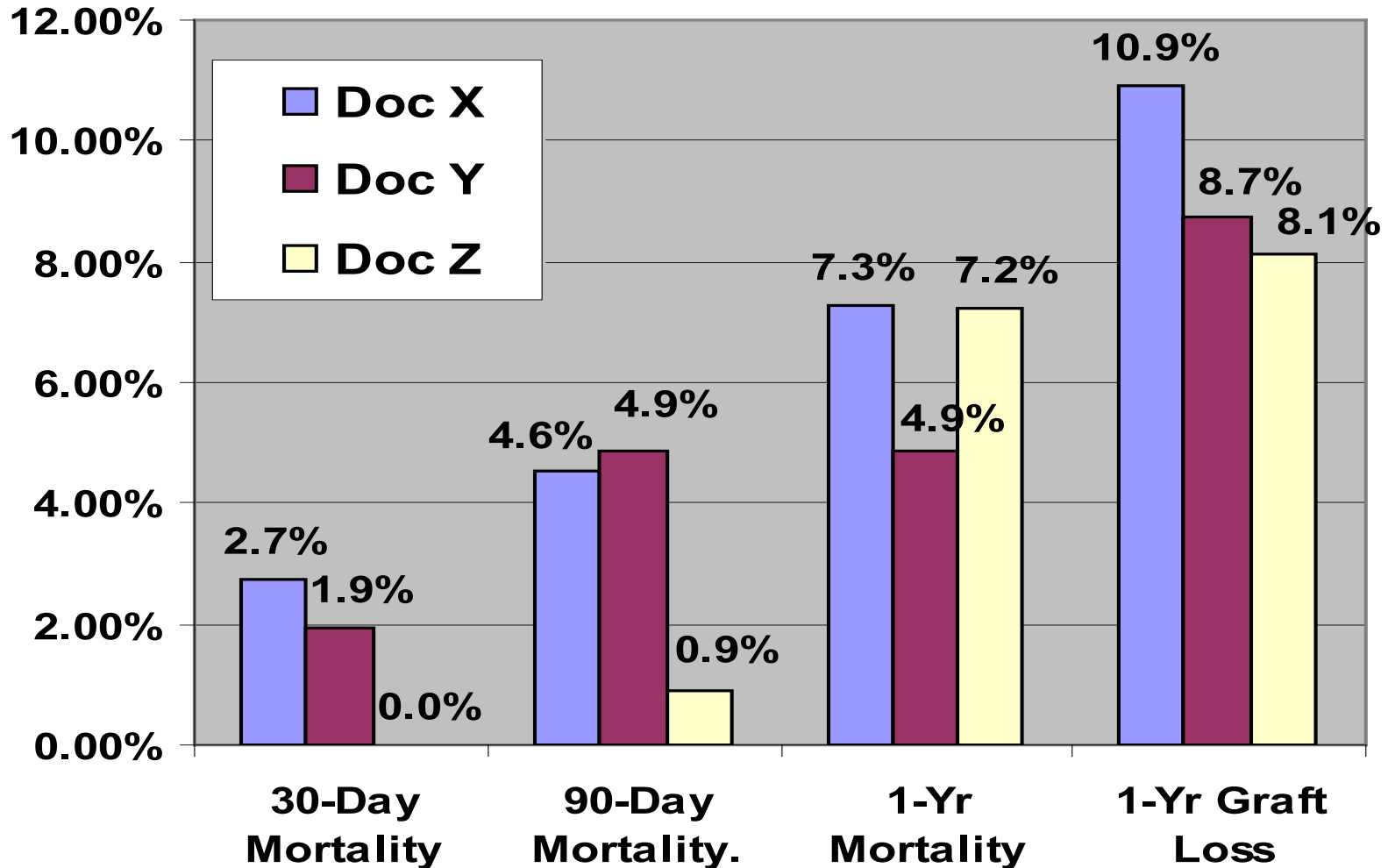
Case Example # 6: Using SRTR Data to Improve the Program

Mortality Rate by Surgeon - Adult Kidney Program - Jan. 2010 SRTR Data



Case Example # 6: Using SRTR Data to Improve the Program

Mortality Rate by Surgeon - Adult Kidney Program - Jan. 2010 SRTR Data



Outcome Trends

for

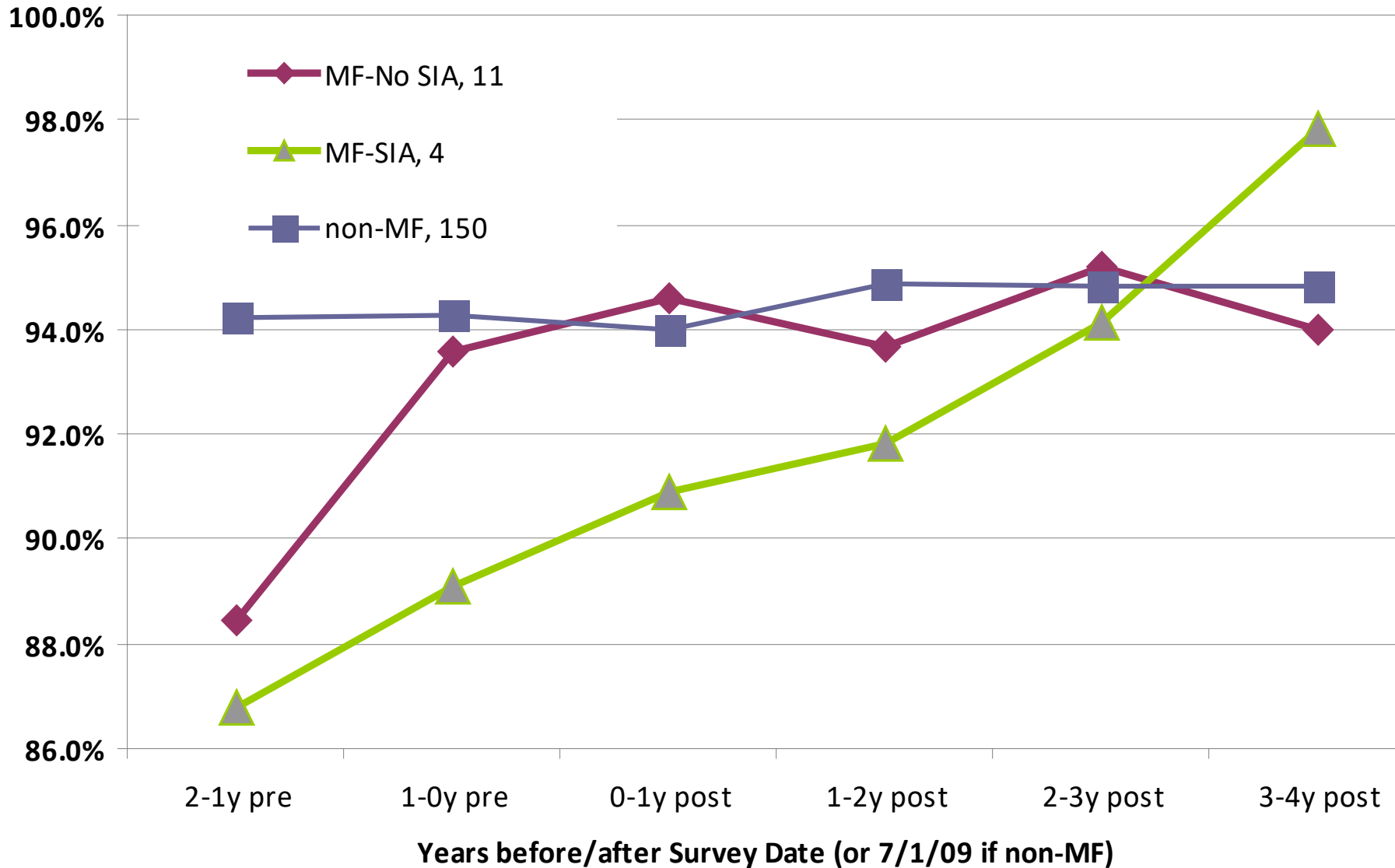
Programs Completing SIAs *and* All Others

Comparison – Programs for Which:

1. Mitigating Factors (MF) was Approved *without* Need for System Improvement Agreement (SIA)
2. SIA was Completed Successfully (= 90% of SIAs)
3. Programs not Cited for Outcomes

Adult Kidney Actual 1-Yr Graft Survival

(All Donors x MF Status, 6 Yrs)



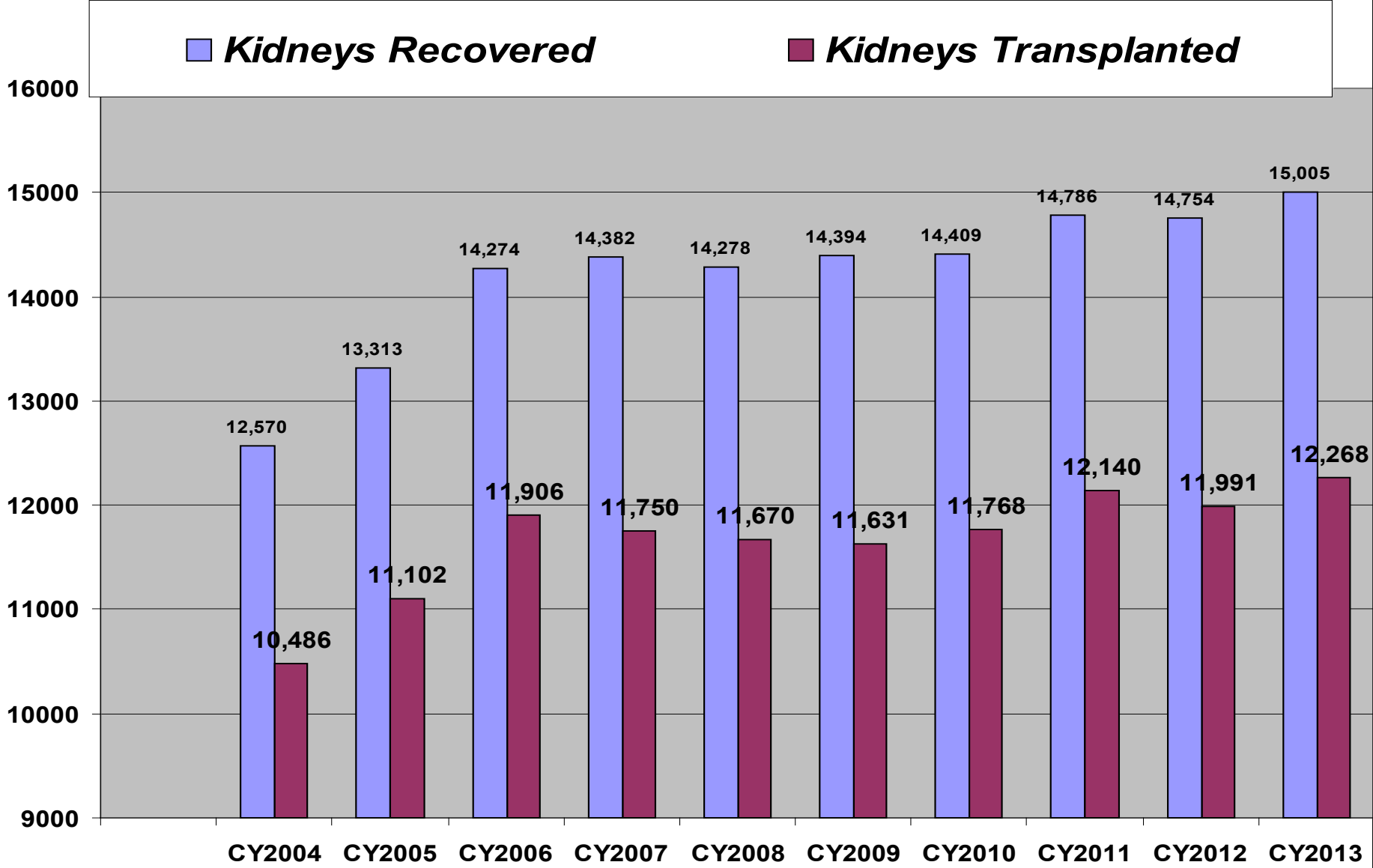
National Trends

- Deceased Donor Volume Slowly Increasing
- Living Donor Volume Decreasing
- Acceptance of Risk is Increasing
 - Organs *and*
 - Recipients

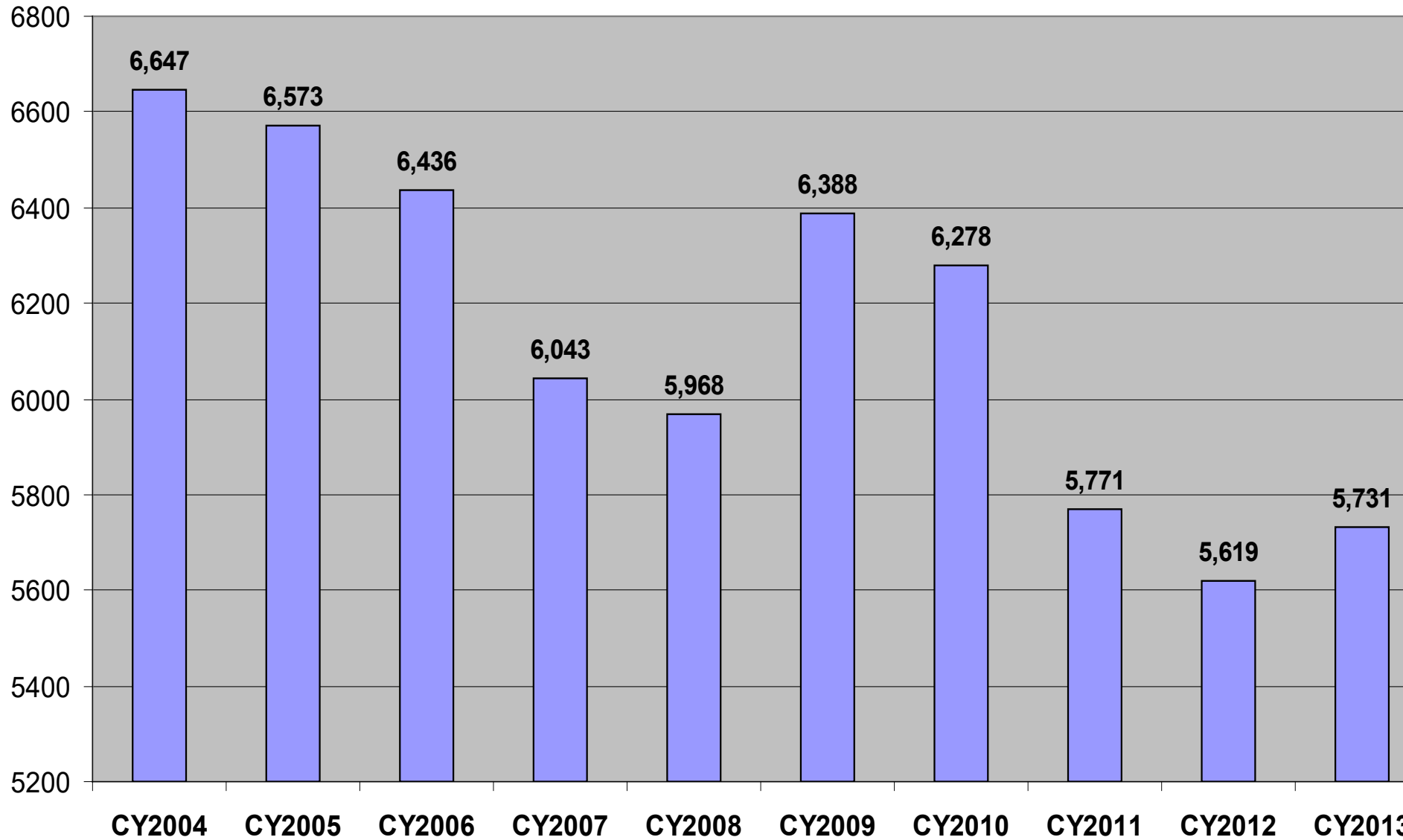
yet

- Outcomes Continue to Improve

Deceased Adult Kidney Transplants CY2004-2013

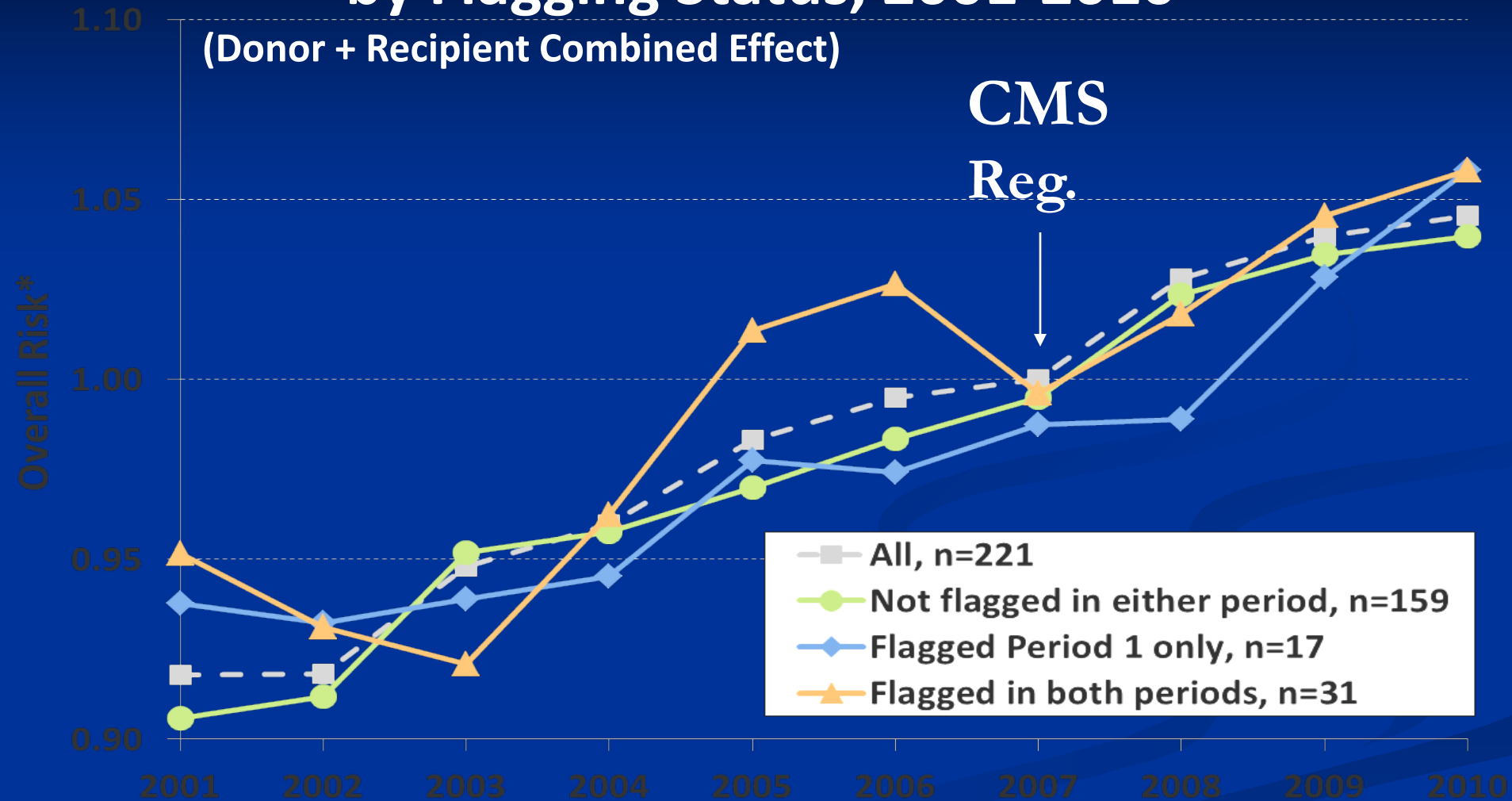


Live Kidney Transplants 2004-2013



Average Overall One-Year Kidney Risk Profile* by Flagging Status, 2001-2010

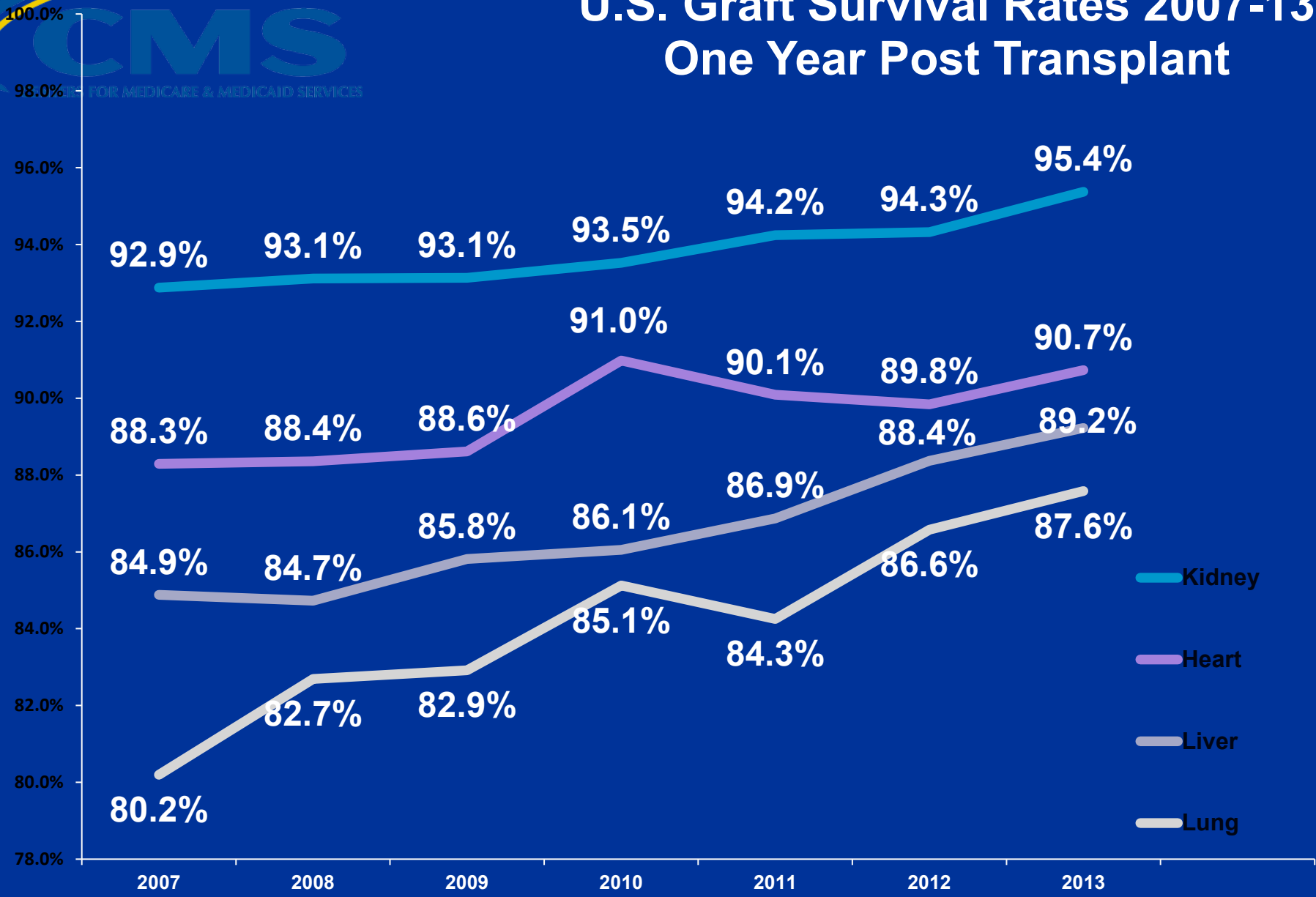
(Donor + Recipient Combined Effect)



* Relative to the average in 2007, overall risk due to the combination of recipient and donor-related factors for adult recipients of deceased donor kidney transplants



U.S. Graft Survival Rates 2007-13 One Year Post Transplant



U.S. Graft Survival Rates 2007-13

One Year Post Transplant

