Public Reporting and Transparency of Outcomes Reporting in Pediatric Cardiac Surgery

Jeffrey P. Jacobs, MD
Professor of Surgery and Pediatrics, Johns Hopkins University
Director, Andrews/Daicoff Cardiovascular Program and Surgical Director of Heart Transplantation
Johns Hopkins All Children’s Hospital

American Society of Extracorporeal Technology (AmSECT)
2018 Pediatric Perfusion Conference
October 4-6, 2018 • Miami EPIC Hotel • Miami, FL
Presented October 6, 2018, 10:30 AM – 11:10 AM

Disclosure

• Chair, STS Workforce on National Databases
• President-elect, Southern Thoracic Surgical Association
• Editor-In-Chief, Cardiology in the Young
• Co-Chair, World Congress of Pediatric Cardiology and Cardiac Surgery 2021

Definition of Quality

- how good or bad something is
- a characteristic or feature that someone or something has:
  something that can be noticed as a part of a person or thing
- a high level of value or excellence


Donabedian’s Triad

Michael Porter

The Healthcare Value Equation

\[
\text{Value} = \frac{\text{Quality}}{\text{Cost}}
\]

value defined as the health outcomes achieved per dollar spent


Basic Principles

1. Variation in outcomes exist

Basic Principles

1. Variation in outcomes exist
2. Patients and their families have the right to know the outcomes of the treatments that they will receive.
Basic Principles

1. Variation in outcomes exist
2. Patients and their families have the right to know the outcomes of the treatments that they will receive.
3. It is our professional responsibility to share this information with them in a format that they can understand.

Adjustment for Case Mix

• Differences in medical outcomes may result from
  1. disease severity,
  2. treatment effectiveness, or
  3. chance.

Basic Principles

- The solution to risk aversive behavior is proper risk adjustment.
- The solution to fear of stifling innovation is proper risk adjustment.
- Our tools for public reporting are not perfect, but they are the BEST available (and these tools will improve)....

Adjustment for Case Mix

• Differences in medical outcomes may result from
  1. disease severity (RISK ADJUSTMENT),
  2. treatment effectiveness, or
  3. chance (CONFIDENCE INTERVALS).

Adjustment for Case Mix

- Differences in medical outcomes may result from
  1. disease severity (RISK ADJUSTMENT),
  2. treatment effectiveness, or
  3. chance (CONFIDENCE INTERVALS).

"Because most outcome studies are observational... risk adjustment is necessary to account for case mix”


1ST TIME PUBLICLY REPORTED

- CABG Composite September 2010
- AVR Composite January 2013
- AVR + CABG Composite August / September 2014
- Pediatric and Congenital Heart Surgery Risk Adjusted Mortality January 2015
- Lobectomy Composite 2017
- MVR Composite 2019
- MVR + CABG Composite 2019
- Esophagotomy Composite 2019
Participation in Public Reporting

### Adult Cardiac Public Reporting Numbers

<table>
<thead>
<tr>
<th>Data Update</th>
<th>Participants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 1</td>
<td>2010 Harvest</td>
<td>Jan 2011</td>
</tr>
<tr>
<td>Round 2</td>
<td>2010 Harvest</td>
<td>Oct/Nov 2011</td>
</tr>
<tr>
<td>Round 3</td>
<td>2011 Harvest</td>
<td>Jan 2012</td>
</tr>
<tr>
<td>Round 4</td>
<td>2012 Harvest</td>
<td>July 2012</td>
</tr>
<tr>
<td>Round 5</td>
<td>2012 Harvest</td>
<td>Jan 2013</td>
</tr>
<tr>
<td>Round 6</td>
<td>2013 Harvest</td>
<td>July 2013</td>
</tr>
<tr>
<td>Round 7</td>
<td>2013 Harvest</td>
<td>Jan 2014</td>
</tr>
<tr>
<td>Round 8</td>
<td>2014 Harvest</td>
<td>July 2014</td>
</tr>
<tr>
<td>Round 9</td>
<td>2014 Harvest</td>
<td>Jan 2015</td>
</tr>
<tr>
<td>10/29/2015</td>
<td>511 / 1093</td>
<td></td>
</tr>
<tr>
<td>3/24/2016</td>
<td>378 / 1134</td>
<td></td>
</tr>
<tr>
<td>4/23/2017</td>
<td>36 / 1095</td>
<td></td>
</tr>
<tr>
<td>9/29/2017</td>
<td>468 / 1,098</td>
<td></td>
</tr>
</tbody>
</table>

Current Numbers (8/6/2018): 704 / 1082 65.0%

### Congenital Public Reporting Numbers

<table>
<thead>
<tr>
<th>Data Update</th>
<th>Participants</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 1</td>
<td>2014 Fall</td>
<td>Harvest</td>
</tr>
<tr>
<td>Round 2</td>
<td>2015 Spring</td>
<td>Harvest</td>
</tr>
<tr>
<td>3/24/2016</td>
<td>68 / 113</td>
<td></td>
</tr>
<tr>
<td>4/23/2017</td>
<td>74 / 117</td>
<td></td>
</tr>
<tr>
<td>9/29/2017</td>
<td>78 / 117</td>
<td></td>
</tr>
</tbody>
</table>

Current Numbers (8/6/2018): 87 / 118 73.7%

Participation in Public Reporting

<table>
<thead>
<tr>
<th>% Enrolled</th>
<th>Unique STS consents / US &amp; Canada participants (as of Friday, September 29, 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Cardiac</td>
<td>59.9% 658 / 1,098</td>
</tr>
<tr>
<td>Congenital</td>
<td>66.6% 78 / 117</td>
</tr>
<tr>
<td>Thoracic</td>
<td>18.1% 52 / 287</td>
</tr>
</tbody>
</table>

Participation in Public Reporting

<table>
<thead>
<tr>
<th>% Enrolled</th>
<th>Unique STS consents / US &amp; Canada participants (as of August 6, 2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Cardiac</td>
<td>65.0% 704 / 1082</td>
</tr>
<tr>
<td>Congenital</td>
<td>73.7% 87 / 118</td>
</tr>
<tr>
<td>Thoracic</td>
<td>27.9% 82 / 293</td>
</tr>
</tbody>
</table>
THE BEGINNING OF STS PUBLIC REPORTING

1) On September 7, 2010, Consumers Union (publisher of Consumer Reports) reported the results of coronary artery bypass grafting (CABG) procedures at 221 U.S. cardiac surgery programs.

2) On January 26, 2011, STS reported the results of coronary artery bypass grafting (CABG) procedures at 226 U.S. cardiac surgery programs.
Composite measure with 2 domains:

1. Absence of operative mortality
2. Absence of major morbidity

No process measures

1. For AVR there are currently no widely accepted process measures as there are for CABG, i.e., medication measures and IMA use

Note: Transcatheter Aortic Valve procedures are not included in the AVR Composite Score
STS AVR Composite Score

<table>
<thead>
<tr>
<th></th>
<th>Fall 2012</th>
<th>Spring 2013</th>
<th>Fall 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6%</td>
<td>3%</td>
<td>2.7%</td>
</tr>
<tr>
<td>2</td>
<td>91%</td>
<td>90%</td>
<td>91.4%</td>
</tr>
<tr>
<td>3</td>
<td>6%</td>
<td>6%</td>
<td>5.9%</td>
</tr>
</tbody>
</table>

STS AVR + CABG Composite Score

Same 2 domains as AVR Composite Score

STS AVR + CABG Composite Score

Same 2 domains as AVR Composite Score

Developing Risk Models:

- When Risk Models were developed by STS for Isolated CABG: the STS-ACSD included > 50,000 Isolated CAB procedures per year
- In a recent one year period in STS-CHSD:
  - VSD closure: n = 1605, 6.3% of all
  - Arterial Switch: n = 453, 1.8% of all
  - Norwood: n = 701, 2.7% of all
- More than 150 unique procedure codes
Building Blocks Towards Transparency

Jeffrey P. Jacobs, M.D., FACS, FACC, FCCP
Professor of Surgery and Pediatrics, Johns Hopkins University
Director, Andrews/Daicoff Cardiovascular Program
Johns Hopkins All Children’s Heart Institute
Johns Hopkins All Children’s Hospital and Florida Hospital for Children

Congenital Heart Disease
Meaningful Multi-institutional Outcomes Analysis

Accomplishments

1) Common Language = Nomenclature
2) Mechanism of Data Collection (Database - Registry)
3) Mechanism of Evaluating Case Complexity
4) Mechanism to Verify Data Validity and Accuracy
5) Collaboration Between Subspecialties
6) Longitudinal Follow-Up and Linked Databases
7) Quality Improvement

The Report of the
2015 STS Congenital Heart Surgery
Practice Survey
- undertaken by the Society of Thoracic Surgeons
- Workforce on Congenital Heart Surgery
- 125 centers in the United States of America perform pediatric and congenital heart surgery
- 8 centers in Canada perform pediatric and congenital heart surgery


STS CHSD: Penetrance in USA

• The STS Congenital Heart Surgery Database (STS-CHSD) is the largest clinical database in the world for congenital and pediatric cardiac surgery.
• The Report of the 2015 Society of Thoracic Surgeons Congenital Heart Surgery Practice Survey, undertaken by the STS Workforce on Congenital Heart Surgery, estimated that 125 hospitals in the United States of America and 8 hospitals in Canada perform pediatric and congenital heart surgery.
• The STS-CHSD contains data from 126 hospitals (close to 100% penetrance by hospital) in the United States of America and 3 of the 8 centers in Canada.

REPRESENTATIVE Congenital Heart Disease
Meaningful Multi-institutional Outcomes Analysis

Accomplishments

1) Common Language = Nomenclature
2) Mechanism of Data Collection (Database - Registry)
3) Mechanism of Evaluating Case Complexity
4) Mechanism to Verify Data Validity and Accuracy
5) Collaboration Between Subspecialties
6) Longitudinal Follow-Up and Linked Databases
7) Quality Improvement

Risk stratification

Risk stratification is a method of analysis in which the data are divided into relatively homogeneous groups (called strata).
**Risk stratification**

- The Aristotle Basic Complexity Levels
  - (ABC Levels)
  - 2002

- The Risk Adjustment for Congenital Heart Surgery Categories
  - (RACHS-1)
  - 2006

- The STS-EACTS Mortality Categories
  - (STAT Mortality Categories)
  - 2010

**Two traditional methodologies for Risk Stratification**

1) Risk Adjustment in Congenital Heart Surgery-1 (RACHS-1)
2) Aristotle Complexity Score
   - Aristotle Basic Complexity Score (ABC Score)
   - Aristotle Comprehensive Complexity Score

---

**STS 2006 Congenital Heart Surgery Database**

- 45,635 cases

---

From Subjective Probability to Objective Data

STAT Mortality Score

The Society of Thoracic Surgeons - European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Score

and

STAT Mortality Categories

The Society of Thoracic Surgeons - European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories


STAT Mortality Categories

Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators.


STAT Mortality Categories

STAT Mortality Score and Categories

were developed based on analysis of 77,294 operations entered in the STS Congenital Heart Surgery Databases and the EACTS Congenital Heart Surgery Database

• EACTS = 33,360 operations
• STS = 43,934 operations

Operations were sorted by increasing risk and grouped into 5 categories that were designed to

• minimize within-category variation
  and
• maximize between-category variation

Combined ECHSA/EACTS and STS Congenital Heart Surgery Databases: 111,494 index cardiac operations

2014 STS Congenital Heart Surgery Database Mortality Risk Model

- All index cardiac operations in the STS-CHSD (January 1, 2010–December 31, 2013) were eligible for inclusion.
- Isolated PDA closures in patients <2.5kg were excluded, as were centers with >10% missing data and patients with missing data for key variables.

52,224 operations from 86 centers were included.
### 2014 STS Congenital Heart Surgery Database Mortality Risk Model

<table>
<thead>
<tr>
<th>Model</th>
<th>Covariates</th>
<th>Development Sample C-Stat</th>
<th>Validation Sample C-Stat</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>STAT Levels</td>
<td>C = 0.772</td>
<td>C = 0.787</td>
</tr>
<tr>
<td>2</td>
<td>STAT Levels + age and weight</td>
<td>C = 0.818</td>
<td>C = 0.817</td>
</tr>
<tr>
<td>3</td>
<td>STAT Levels + age and weight + patient factors</td>
<td>C = 0.862</td>
<td>C = 0.852</td>
</tr>
<tr>
<td>Final Model</td>
<td>Primary procedure + age and weight + patient factors</td>
<td>C = 0.875</td>
<td>C = 0.858</td>
</tr>
</tbody>
</table>
2014 STS Congenital Heart Surgery Database Mortality Risk Model

<table>
<thead>
<tr>
<th>Model</th>
<th>Covariates</th>
<th>Development Sample C-Stat</th>
<th>Validation Sample C-Stat</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>STAT Levels</td>
<td>C = 0.772</td>
<td>C = 0.787</td>
</tr>
<tr>
<td>2</td>
<td>STAT Levels + age and weight</td>
<td>C = 0.818</td>
<td>C = 0.817</td>
</tr>
<tr>
<td>3</td>
<td>STAT Levels + age and weight + patient factors</td>
<td>C = 0.862</td>
<td>C = 0.852</td>
</tr>
<tr>
<td></td>
<td>Final Model</td>
<td>Primary procedure + age and weight</td>
<td>C = 0.846</td>
</tr>
<tr>
<td></td>
<td>Final Model</td>
<td>Primary procedure + age and weight + patient factors</td>
<td>C = 0.875</td>
</tr>
</tbody>
</table>

Fig 1. Distribution of hospital-specific observed-to-expected (O/E) ratios for operative mortality with 95% confidence intervals (grey lines).
Fig 1. Distribution of hospital-specific observed-to-expected (O/E) ratios for operative mortality with 95% confidence intervals (gray lines).

2014 STS Congenital Heart Surgery Database Mortality Risk Model

What about Confidence Intervals

<table>
<thead>
<tr>
<th>Confidence Interval</th>
<th>Total Programs</th>
<th>Programs with higher than expected mortality</th>
<th>Programs with same as expected mortality</th>
<th>Programs with lower than expected mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>80% Confidence Intervals</td>
<td>86 (100%)</td>
<td>19 (22%)</td>
<td>67 (78%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>90% Confidence Intervals</td>
<td>86 (100%)</td>
<td>13 (15%)</td>
<td>63 (73%)</td>
<td>10 (12%)</td>
</tr>
<tr>
<td>95% Confidence Intervals</td>
<td>86 (100%)</td>
<td>12 (14%)</td>
<td>67 (78%)</td>
<td>7 (8%)</td>
</tr>
<tr>
<td>99% Confidence Intervals</td>
<td>86 (100%)</td>
<td>6 (7%)</td>
<td>78 (91%)</td>
<td>2 (2%)</td>
</tr>
</tbody>
</table>
What about Confidence Intervals

<table>
<thead>
<tr>
<th>Total Programs</th>
<th>Programs with higher-than-expected mortality</th>
<th>Programs with same-as-expected mortality</th>
<th>Programs with lower-than-expected mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
<td>Number (%)</td>
</tr>
<tr>
<td>80% Confidence Intervals</td>
<td>86 (100%)</td>
<td>19 (22%)</td>
<td>52 (60%)</td>
</tr>
<tr>
<td>90% Confidence Intervals</td>
<td>86 (100%)</td>
<td>13 (15%)</td>
<td>63 (73%)</td>
</tr>
<tr>
<td>95% Confidence Intervals</td>
<td>86 (100%)</td>
<td>12 (14%)</td>
<td>67 (78%)</td>
</tr>
<tr>
<td>99% Confidence Intervals</td>
<td>86 (100%)</td>
<td>6 (7%)</td>
<td>78 (91%)</td>
</tr>
</tbody>
</table>
### What about Confidence Intervals

<table>
<thead>
<tr>
<th>Confidence Intervals</th>
<th>Number (%)</th>
<th>Number (%)</th>
<th>Number (%)</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90%</td>
<td>86 (100%)</td>
<td>19 (22%)</td>
<td>52 (60%)</td>
<td>15 (17%)</td>
</tr>
<tr>
<td>95%</td>
<td>86 (100%)</td>
<td>13 (15%)</td>
<td>63 (73%)</td>
<td>10 (12%)</td>
</tr>
<tr>
<td>99%</td>
<td>86 (100%)</td>
<td>6 (7%)</td>
<td>78 (91%)</td>
<td>2 (2%)</td>
</tr>
</tbody>
</table>

### STS Congenital Heart Surgery Database Participants

#### January 1, 2011 to December 31, 2014

- **One Star Programs** = 11
- **Two Star Programs** = 79
- **Three Star Programs** = 6
- **No Star Rating** = 20

#### STS Congenital Heart Surgery Database Participants

#### January 1, 2014 to December 31, 2017

- **One Star Programs** = 13
- **Two Star Programs** = 85
- **Three Star Programs** = 12
- **No Star Rating** = 9
STS Congenital Heart Surgery Database Participants
January 1, 2014 to December 31, 2017

- One Star Programs = 10 out of 13
- Two Star Programs = 63 out of 85
- Three Star Programs = 12 out of 12
- No Star Rating = 9

“Science tells us what we can do;
Guidelines what we should do; &
Registries what we are actually doing.”

Lukas Kappenberger MD
Heart Rhythm Society Policy Conference
Washington DC 2005

“Without data you’re just another person with an opinion.”

- W. Edwards Deming, Data Scientist