Update to STAT Scores

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Nothing to Disclose
Nothing to disclose
Background

I. A primary objective of STS CHSD is Reporting Outcomes to participating centers in a way that enables them to understand their own outcomes, both in isolation, and in the context of the aggregate outcomes of all database participants. Ideally, this “quality assessment element” also serves as a platform for quality improvement.
Background

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II. Making sense of reported outcomes requires an understanding of “Case Mix,” and some reliable means of accounting for Case Mix when analyzing outcomes.
a. Reporting of raw, unadjusted mortality data may be misleading and potentially penalizes surgeons and centers that manage high-risk patients and perform complex procedures, because observed mortality rates might be higher than in centers dealing with less challenging cases.

b. The kinds of statistical tools and risk models that have been developed to address these issues when the clinical substrate is adult patients with acquired cardiovascular disease cannot simply be applied to the population of pediatric and adult patients with congenital heart disease. Here the problem is considerably more complex, in large part because the individual diagnoses and distinct types of surgical procedures number in the hundreds, despite the fact that the universe of patients with congenital heart disease is considerably smaller than that of adult patients with ischemic and valvular heart disease. As a result, the number of patients in some diagnostic and procedural groups is quite small.
Historical Precedent:

- Aristotle Basic Complexity Score (ABC Score; 2000) developed by panel of experts; *doxa*

- RACHS-1 (2002); 6 levels of increasing risk of mortality; primary source – expert panel, subsequently refined using empirical data from 2 multi-institutional registries

- RACHS showed higher discrimination for predicting mortality; ABC Score covered a larger proportion of congenital heart surgery case volume
“Original” STAT (STS-EACTS) Metric 2009

a. Relied upon empirical data rather than expert opinion
b. Estimated procedure-specific relative risks of mortality using a statistical model that accounts for uncertainty in procedures with small sample size
c. Converted these procedure-specific mortality estimates into a scale ranging from 0.1 to 5.0
d. Grouped procedures with similar estimated mortality risk into a small number of relatively homogeneous categories (the number to be determined on the basis of optimizing within category homogeneity and between category difference).
Why do this? Why the stratification into relatively homogeneous categories?

- Even back when Aristotle and RACHS were developed, there were ≈ 140-150 congenital heart surgery procedures to be accounted for in considerations of case mix adjustment.

- Even when looking at more commonly performed procedures, such as 8 “benchmark operations” (really groups of operations, e.g. 4 types of Fontan operations, 3 types of TOF repair), it was apparent that despite looking at 5 years of data, many individual operations are not performed frequently enough at any given institution to discriminate levels of performance, i.e. to ascertain whether a given center has outcomes that are significantly different (better or worse) in relation to the ALL-STS aggregate.

- Statistically meaningful assessment of differences in mortality at center level could be made only for the Norwood procedure. For the remainder of the benchmark operations, the constraints related to small sample size and overall low number of events (deaths) made it impossible to make statistically meaningful inferences concerning mortality differences across centers.
Fig 1. Mortality data displayed as funnel plots for these 8 benchmark operations. The horizontal dashed line depicts aggregate STS mortality prior to discharge for the given lesion. Dashed lines depicting exact 95% binomial prediction limits were overlaid to make a funnel plot. Squares represent the number of cases and mortality prior to discharge for individual STS Congenital Heart Surgery Database Participants (Centers). (A) ventricular septal defect (VSD) repair; (B) tetralogy of Fallot (TOF); (C) arterial switch operation (ASO); (D) ASO + VSD; (E) complete atrioventricular canal (AVC) repair; (F) Fontan operation; (G) truncus arteriosus repair; (H) Norwood procedure.

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b. Mortality risk was estimated for 148 types of operative procedures using data from 77,294 operations entered into the European Association for Cardiothoracic Surgery (EACTS) Congenital Heart Surgery Database (33,360 operations) and the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (43,934 patients) between 2002 and 2007. Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators.

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c. Each procedure was assigned a numeric score (the STS–EACTS Congenital Heart Surgery Mortality Score [2009]) ranging from 0.1 to 5.0 based on the estimated mortality rate. Procedures were also sorted by increasing risk and grouped into 5 categories (the STS–EACTS Congenital Heart Surgery Mortality Categories [2009]) that were chosen to be optimal with respect to minimizing within-category variation and maximizing between-category variation.

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d. STS-EACTS (STAT) Mortality Categories compared favorably (higher discrimination expressed as c-index) relative to Aristotle and RACHS-1. They also encompassed many more procedures in STS CHSD.
f. At the time of initial development of STAT Mortality Scores and STAT Mortality Categories, mortality was determined only on the basis of status at the time of discharge (Discharge Mortality).
So, what was the next step?

Analysis of variation in outcomes for groups of risk stratified operations (STAT Mortality Categories) using funnel plots with 95% prediction limits. This revealed that it was possible to identify centers characterized as outliers for procedures grouped within each STAT Mortality Category.
Fig 3. Mortality data displayed as a funnel plot for STAT Category 3 operations. The horizontal dashed line depicts aggregate STS mortality before discharge. Dashed lines depicting exact 95% binomial prediction limits were overlaid to make a funnel plot. Squares represent the number of cases and mortality before discharge for individual STS Congenital Heart Surgery Database participants (centers). (STAT = The Society of Thoracic Surgeons [STS]-European Association for Cardio-Thoracic Surgery [EACTS] Congenital Heart Surgery Mortality Categories.)

Fig 4. Mortality data displayed as a funnel plot for STAT Category 4 operations. The horizontal dashed line depicts aggregate STS mortality before discharge. Dashed lines depicting exact 95% binomial prediction limits were overlaid to make a funnel plot. Squares represent the number of cases and mortality before discharge for individual STS Congenital Heart Surgery Database participants (centers). (STAT = The Society of Thoracic Surgeons [STS]-European Association for Cardio-Thoracic Surgery [EACTS] Congenital Heart Surgery Mortality Categories.)
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- The numbers were as follows: Category 1 = 3 (4.1%), Category 2 = 1 (1.4%), Category 3 = 7 (9.7%), Category 4 = 13 (17.8%), and Category 5 = 13 (18.6%).

- The process enabled the identification of both “positive” and “negative” outliers. The study confirmed that grouping of operations into strata of similar risk facilitates analysis of outcomes with identification of centers with similar, higher, and lower center-level mortality rates relative to aggregated “ALL STS” outcomes for operations within each stratum of risk – findings which can aid in quality assessment and quality improvement initiatives.
New Procedures Codes

Facts about STAT Mortality Scores/Categories

- For 148 procedures STAT Mortality Scores and Categories were empirically derived based entirely on objective data. There are approximately 50 additional procedure codes to which STAT Scores/Categories have been subsequently assigned on the basis of a consensus process of the STS CHSD Task Force, when these new procedure codes were introduced into the STS CHSD Data Collection Form (DCF) at the time of data upgrades (Versions 3.0 [26 procedures], 3.22 [16 procedures] and 3.3 [7 procedures]).
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• For example, in 2016, a panel of experienced congenital heart surgeons (members of the STS CHSD Task Force) from programs representing a variety of programmatic volume categories were surveyed and asked to provide STAT Mortality Scores for 7 procedures that were new to version 3.3, relying on their own experience and published data, and using existing STAT scores as a guide. For each new procedure code, the mean of the scores suggested by these seventeen surgeons was used to assign the STAT Mortality Score and STAT Mortality Category for these 7 new procedures.
Use of STAT Scores/Categories in STS CHSD Feedback Reports to Participants

• Table 1: a 4-year summary of center-level and STS-wide data stratified by STAT Mortality Category, including (1) operations entered into the STS CHSD, (2) patients included in the analysis, and (3) operations eligible for mortality analysis, and (4) Operative Mortality percent with 95% CI. Participant data is juxtaposed to ALL STS data. For the ALL STA data display, records received by the database are pooled together as if they were a ‘super site’ that performed all of the operations in the STS Congenital Heart Surgery Database

• Table 3: Operative Mortality, stratified by STAT Mortality Category, for each Participant, for the Last 4 Years (all de-identified, arranged by center volume).

• Figures 2-6: funnel plots depicting Operative Mortality, for each STAT Mortality Category (1,2,3,4,and 5) by Participant, for the last 4 Years, showing overall value for STS and individual observed mortality rates with 95% CI for each center (de-identified)
Figures 2-6 are funnel plots depicting: Operative Mortality, for each STAT Mortality Category (1, 2, 3, 4, and 5) by Participant, for the last 4 Years, showing overall value for STS and individual observed mortality rates with 95% CI for each center (de-identified).

**Figure 5: Operative Mortality, by STAT Mortality Category 4, by Participant, Last 4 Years, (Jan 2014 - Dec 2017)**

Operative Mortality + 95% CI
Use of STAT Scores/Categories in STS CHSD Feedback Reports to Participants

• Figure 7 depicts Operative Mortality, for each STAT Mortality Category, at the level of the Database Participant, last 4 Years, showing center-level observed Operative Mortality rate w/ 95% CI, and STS average center-level mortality rate, and STS range, median, and 10th and 90th percentile values. Participant mortality may be compared to the benchmark mean (black dot) and median (50th percentile in Figure 7) results of all participants.
• Table 7 presents similar data to that in Table 1, with the added fact that these data are now stratified by age categories (neonate, infant, child, adults), as well as STAT Mortality categories, and also reported for both the 48-month harvest window and also the most recent 12 months.
Table 16 presents **Participant Operative Mortality**; Observed and Expected Mortality rates, O:E ratio with 9% CI, Adjusted Mortality Rate (95% CI), last four years. Inclusion criteria for Model 1 stipulate that “The operation includes procedure(s) with a defined STAT Mortality Category.” The **Mortality Risk Model adjusts for each combination of primary procedure and age group.** STAT Category is NOT a primary covariate in the model. Coefficients are obtained via shrinkage estimation with the STAT Mortality Category [6] as an auxiliary variable.
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• Table 19 presents **Risk Stratified Operations**: Overall STS Aggregate and Participant-Specific Mortality and Postoperative Length of Stay, Last 4 Years. In this table, observed mortality rates and data about postoperative length of stay are stratified by STAT Mortality Category. These data are not “risk-adjusted” (unlike Table 16, which relies upon STS CHSD Mortality Risk Model with both procedural and patient factors); however, these data are risk-stratified using the STAT Mortality Categories.
One of the most important things about the STAT Scores and Categories....
Updating the STAT Scores and Categories

To serve as a reliable metric for stratification of operations on the basis of statistically estimated risk of Operative Mortality, the STAT Scores and Categories should be:
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To serve as a reliable metric for stratification of operations on the basis of statistically estimated risk of Operative Mortality, the STAT Scores and Categories should be:

1. **Empirically based** for all procedures
2. Derived using contemporary data
3. Reliant upon the **current definition of Operative Mortality** as endpoint
4. Reliant on an **updated approach to multiple component operations**
A Few Examples of Procedure Codes for which Current STAT Scores *are not Empirically Based*

<table>
<thead>
<tr>
<th>Score</th>
<th>Category</th>
<th>Procedure Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.6</td>
<td>2</td>
<td>Kawashima operation (superior cavopulmonary connection in setting of interrupted IVC with azygous continuation)</td>
</tr>
<tr>
<td>0.6</td>
<td>2</td>
<td>Fontan, TCPC, External conduit, hepatic veins to pulmonary artery, Nonfenestrated</td>
</tr>
<tr>
<td>0.8</td>
<td>3</td>
<td>Removal of transcatheter delivered device from heart</td>
</tr>
<tr>
<td>1.3</td>
<td>4</td>
<td>Unifocalization MAPCA(s), Unilateral pulmonary Unifocalization</td>
</tr>
<tr>
<td>2.1</td>
<td>4</td>
<td>Pulmonary atresia - VSD - MAPCA repair, Status post prior incomplete unifocalization (includes completion of pulmonary unifocalization + VSD closure + RV to PA connection [with or without conduit])</td>
</tr>
<tr>
<td>2.3</td>
<td>4</td>
<td>Pulmonary atresia - VSD - MAPCA repair, Complete single stage repair (1-stage that includes bilateral pulmonary unifocalization + VSD closure + RV to PA connection [with or without conduit])</td>
</tr>
<tr>
<td>2.6</td>
<td>4</td>
<td>Hybrid Approach &quot;Stage 1&quot;, Application of RPA and LPA bands</td>
</tr>
<tr>
<td>3.1</td>
<td>5</td>
<td>Hybrid Approach &quot;Stage 1&quot;, Stent placement in arterial duct (PDA) + application of RPA and</td>
</tr>
<tr>
<td>4.1</td>
<td>5</td>
<td>Hybrid approach &quot;Stage 2&quot;, Aortopulmonary amalgamation + Superior Cavopulmonary anastomosis(es) + PA Debanding + Aortic arch repair (Norwood [Stage 1] + Superior Cavopulmonary anastomosis(es) + PA Debanding)</td>
</tr>
</tbody>
</table>
Updated STAT Score
Should be derived using contemporary data

• Congenitally corrected TGA repair, atrial switch and ASO (double switch):
  2009 STAT dataset; 32 operations, observed mortality of 25%
  model based mortality estimate of 20.0% (9.1%–34.7%)

• Last feedback report; 2015 – 2018 data
  114 operations, observed mortality of 3.5%

Should the STAT Score for this procedure be different than the one based on data that are now > 10 years old?
Updated STAT Score
Should rely on current definition of Operative Mortality

In 2009, status at hospital discharge was the basis for ascertainment of Operative Mortality.

Since then, STS CHSD has revised this, now relies upon: 30-day status, and status at Date of Database Discharge.
Should be revised (updated) in terms of approach to multiple component operations

At the time that the STS-EACTS Mortality Score and Categories were originally developed, investigators confronted the need to identify the procedure on which the statistically estimated mortality risk of a multiple procedure operation would be based (at least 11,000 unique procedure combinations were identified in the data within the STS CSD for the period of interest).

It was decided at the time that the “technical difficulty” component of the Aristotle Score would be used to identify the component procedure that would be the basis for classification.
Should be revised (updated) in terms of approach to multiple component operations

In order to insure that multiple component operations are evaluated in a fashion that most accurately assigns STAT Mortality Score and Category designations based on the statistically estimated risk of mortality, the “technical difficulty” criterion is now felt to be sub-optimal (there are clearly technically demanding operations that are nonetheless associated with relatively low rates of operative mortality; e.g. Ross operation). Since this is a “mortality metric” it makes sense that multiple component operations be identified on the basis of the component procedure which is, itself, associated with the highest risk of mortality.
Should be revised (updated) in terms of approach to multiple component operations

The premise, or predicate for the first phase of the STAT Update Project:

While there are approximately 200 unique procedure codes for cardiovascular surgical procedures that are eligible to be a primary procedure in the STS CHSD, there are 20,000+ unique procedure combinations encountered in the data from January 1, 2010 – June 30, 2017. Among these, there are some multiple component operations for which the statistically estimated risk of mortality is likely to be different from that of the highest risk component procedure.
We embarked on a set of analyses to identify procedure combinations that may require special handling when estimating their average mortality risk for the assignment of STAT categories. In particular, we sought to identify procedure combinations whose average mortality risk cannot be adequately approximated by assuming it is equal to the average mortality risk of the combination's highest-risk individual component procedure.

Based on some exploratory analyses, and following unanimous consensus of the STAT Update Working Group, we adopted the following threshold parameters:

- Relative difference ratio $\geq 1.25$
- Probability $\geq 90$
- Denominator $\geq 5$
Operation-level inclusion/exclusion criteria

- Include operations performed during January 1, 2010 – June 30, 2017
- Exclude operations not eligible for STS-CHSD Mortality analyses: patients weighing ≤ 2.5kg undergoing isolated PDA closure; neonates undergoing pacemaker procedures, MCS procedures
- Only include cardiac operations, defined as those with at least one component procedure of Operation Type CPB (or CPB Cardiovascular) or No CPB Cardiovascular
- Only include first cardiovascular surgical operations (i.e. the index operation)
- Only include records with operation-level data collected in v3.0 or later
- Only include patients with non-missing Operative Mortality
PROCEDURES NOT ELIGIBLE FOR CONSIDERATION (i.e. ignored entirely)

1) Interventional Cardiology Procedures, Fetal Interventions (now being deleted from Data Collection Form [DCF] Procedure Codes [in the upgrade operationalized in 2019])

2) “Anesthetic Procedures” (Non-cardiovascular Non-thoracic procedure on cardiac patient with cardiac anesthesia, Echocardiography Procedures, and Radiology Procedures)

3) Vague codes that don’t lend themselves to meaningful interpretation in terms of potential association with risk (e.g. Cardiotomy other, Cardiac procedure other, Thoracotomy other, Miscellaneous other, Other procedure).

4) Mechanical Support Procedures (excluded from STS CHSD Mortality Calculations)*
PROCEDURES NOT IGNORED, BUT NOT ELIGIBLE FOR CONSIDERATION AS HIGHEST RISK COMPONENT OF A MULTIPLE PROCEDURE OPERATION

Similar in concept to the “Op Type Cleanup Process” (2016) which established of a list of procedures that can NEVER be the Primary Procedure of a Cardiovascular Surgical Operation.

In the context of this STAT Update analysis, certain procedures
• are relevant as concomitant procedures in the process to identify “procedure combinations with high probability of exceeding a specified relative difference (in mortality risk) compared to highest risk component procedure”, but...
• are not considered in the identification of the highest risk component procedure.
Examples of PROCEDURES NOT IGNORED, BUT NOT ELIGIBLE FOR CONSIDERATION AS HIGHEST RISK COMPONENT OF A MULTIPLE PROCEDURE OPERATION

- 1400= Lung biopsy
- 1440= Tracheal procedure
- 1820= Pleural procedure, Other
- 1830= Ligation, Thoracic duct
- 1840= Decortication
- 1850= Esophageal procedure
- 1860= Mediastinal procedure
- 1870= Bronchoscopy
- 1880= Diaphragm plication
- 1890= Diaphragm procedure, Other
So finally, a few months ago, we completed the phase of analysis to identify procedure combinations whose average mortality risk cannot be adequately approximated by assuming it is equal to the average mortality risk of the combination’s highest-risk individual component procedure.

In addition to the 200+ eligible procedure codes in the Data Collection Form (as of version 3.3), the combination procedure codes identified by this process will be included in the model to estimate procedure-based mortality risk.
Examples:

540+1590: PA reconstruction (plasty), Branch, Central (within the hilar bifurcation) + Shunt, Systemic-to-pulmonary, Modified Blalock-Taussig Shunt (MBTS)

440+610: Unifocalization MAPCA(s) + Conduit placement, RV to PA

610+720: Conduit placement, RV to PA + Aortic root replacement, Mechanical

1370+1440: Pulmonary artery sling repair + Tracheal procedure

440+1600: Unifocalization MAPCA(s) + Shunt, Systemic-to-pulmonary, Central (shunt from aorta)

1330+2200: PDA closure, Surgical + TAPVC repair + Shunt - systemic-to-pulmonary
Approaching the Final Phases of Development of the NEW STAT Scores and Categories

Mortality risk will be estimated for each of the 230+ distinct procedure codes using data from all operations in which these procedure codes occur.

After estimating procedure-specific mortality risks, multiple-procedure operations will be assigned to the procedure type with the highest estimated mortality risk. Note that this assignment is made after the estimation step above. Note also that these analyses do not rely upon the previous existing primary procedure algorithm used in generating feedback reports.
Approaching the Final Phases of Development of the NEW STAT Scores and Categories

After estimating procedure-specific mortality risks, scores will be determined by re-scaling the risk estimates to lie between 0.1 and 5.0

Based on these scores, procedures will be stratified into 5 categories, that are designed to maximize within-category homogeneity of estimated mortality risks.
Within-Category Homogeneity

Number of Categories

0.958 (5 categories)

Not final; based on preliminary model development
So, you’re thinking, “Cool, tell us more about the Updated STAT Scores and Categories...”
Updated STAT Scores and Categories

• Will ALL be empirically derived
• Will be based on more contemporary practice and outcomes data
• Will rely upon the current STS CHSD definition of Operative Mortality
• Will rely on an updated approach to multiple component operations that is driven by actual procedural risk rather than technical difficulty
• There will be MORE procedure codes with “new” STAT scores
There will be MORE procedure codes with STAT scores

- 200+ procedure codes from the DCF
- 30+ unique procedure combinations shown to have mortality risk that cannot be adequately approximated by assuming it is equal to the average mortality risk of the combination's highest-risk individual component procedure...
- ....and, ALL empirically derived.
Updated STAT Scores and Categories

Coming soon to a theatre near you...
Updated STAT Scores and Categories...

...will revisit, and will fulfill the original objectives for development of the STAT Scores and Categories envisioned a decade ago: “The goal (then and now) was to create an objective, empirically based index that can be used to identify the statistically estimated risk of mortality by procedure and to group procedures into risk categories.”
Thank you for your attention