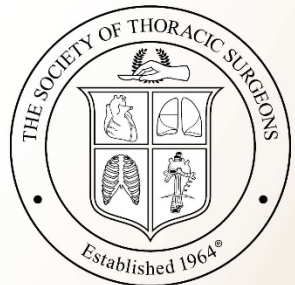# Intraoperative Complications – Defining the Fields

Jeffrey P. Jacobs, MD

Intraoperative Complications – Defining the Fields

Jeffrey P. Jacobs, MD

**To prepare for this talk,
I reviewed 7 sources of information about pediatric and congenital cardiac surgical complications**

Original Article

The nomenclature of safety and quality of care for patients with congenital cardiac disease: a report of the Society of Thoracic Surgeons Congenital Database Taskforce Subcommittee on Patient Safety

Jeffrey Phillip Jacobs,[1] Oscar J. Benavidez,[2] Emile A. Bacha,[2] Henry L. Walters III,[3] Marshall Lewis Jacobs[4]

[1]The Congenital Heart Institute of Florida (CHIF), Division of Thoracic and Cardiovascular Surgery, All Children's Hospital and Children's Hospital of Tampa, University of South Florida College of Medicine, Cardiac Surgical Associates (CSA), Saint Petersburg and Tampa, Florida, United States of America; [2]Children's Hospital Boston, Harvard Medical School, Boston, Massachusetts, United States of America; [3]Children's Hospital of Michigan, Wayne State University School of Medicine, Detroit, Michigan, United States of America; [4]Drexel University College of Medicine, Philadelphia, Pennsylvania, United States of America

Abstract A large body of literature devoted to "patient safety" and error prevention exists and utilizes a nomenclature that can be applied specifically to the field of congenital cardiac disease and aid in the goals of increasing the safety of patients, decreasing medical error, minimizing mortality and morbidity, and evaluating quality of care. The purpose of this manuscript is to suggest and document a quality of health care taxonomy and the appropriate application of this nomenclature of "patient safety" to the specialty of congenital cardiac disease, with special emphasis on the following ten terms: morbidity, complication, medical error, adverse event, harm, near miss, iatrogenesis, iatrogenic complication, medical injury, and sentinel event. Each of these terms is commonly utilized in the medical literature without universal agreement on their meaning and relationship. It is our hope that the standardization of the definitions of these terms, as they are applied to the analysis of outcomes of the treatments applied to patients with congenital and paediatric cardiac disease, will facilitate improved methodologies to assess and improve quality of care in our profession.

Keywords: Congenital heart disease; complications; medical error; surgical outcomes; registry

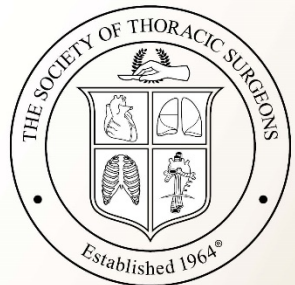GIVEN THAT MORTALITY FOLLOWING SURGERY FOR congenital and paediatric cardiac disease has fallen substantially, those providing medical and surgical treatment for patients with congenitally done to prevent or mitigate the morbidity and mortality that would result from congenital cardiac disease if no therapeutic intervention is performed. Surgical care of congenital cardiac disease invariably
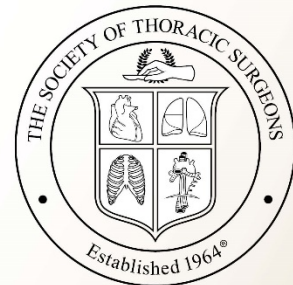
Complication

"A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome".

Complication

‚‚A complication is an event or occurrence **that is associated with a disease or a healthcare intervention**, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome''.

Complication

This definition of complication recognizes that a complication can be secondary to multiple etiologies including the following three:

1. The patient's **underlying disease itself**, independent of health care interventions

2. Diagnostic, palliative, therapeutic, and preventative **health care interventions**

3. Any combination of the two choices above.

Complication

- An example of a complication caused by the patient's underlying disease is a **spontaneous pneumothorax** developing in a patient with pulmonary blebs.

- An example of a complication secondary to a health care intervention is a **pneumothorax caused by an inadvertent pleural puncture** during a subclavian central line placement.

Complication

"A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and **may cause, or be associated with, suboptimal outcome**".
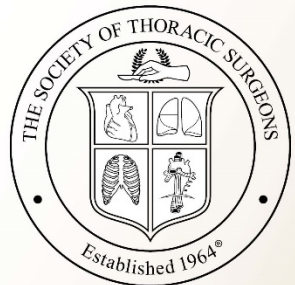
Complication

- This definition also recognizes that not all complications cause or are associated with suboptimal outcome.

Adverse event

- ''An adverse event is a complication that is associated with a healthcare intervention and is associated with suboptimal outcome.''

An empirically based tool for analyzing mortality associated with congenital heart surgery

Sean M. O'Brien, PhD,[a] David R. Clarke, MD,[b] Jeffrey P. Jacobs, MD,[c] Marshall L. Jacobs, MD,[d]
Francois G. Lacour-Gayet, MD,[b] Christian Pizarro, MD,[e] Karl F. Welke, MD,[f] Bohdan Maruszewski, MD,[g]
Zdzislaw Tobota, MD,[h] Weldon J. Miller, MD,[i] Leslie Hamilton, MD,[j] Eric D. Peterson, MD, MPH,[a]
Constantine Mavroudis, MD,[d] and Fred H. Edwards, MD[k]

Objective: Analysis of congenital heart surgery results requires a reliable method of estimating the risk of adverse outcomes. Two major systems in current use are based on projections of risk or complexity that were predominantly subjectively derived. Our goal was to create an objective, empirically based index that can be used to identify the statistically estimated risk of in-hospital mortality by procedure and to group procedures into risk categories.

Methods: 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. 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. Model performance was subsequently assessed in an independent validation sample (n = 27,700) and compared with 2 existing methods: Risk Adjustment for Congenital Heart Surgery (RACHS-1) categories and Aristotle Basis Complexity scores.

Results: Estimated mortality rates ranged across procedure types from 0.3% (atrial septal defect repair with patch) to 29.8% (truncus plus interrupted aortic arch repair). The proposed STS–EACTS score and STS–EACTS categories demonstrated good discrimination for predicting mortality in the validation sample (C-index = 0.784 and 0.773, respectively). For procedures with more than 40 occurrences, the Pearson correlation coefficient between a procedure's STS–EACTS score and its actual mortality rate in the validation sample was 0.80. In the subset of procedures for which RACHS-1 and Aristotle Basic Complexity scores are defined, discrimination was highest for the STS–EACTS score (C-index = 0.787), followed by STS–EACTS categories (C-index = 0.778), RACHS-1 categories (C-index = 0.745), and Aristotle Basic Complexity scores (C-index = 0.687). When patient covariates were added to each model, the C-index improved: STS–EACTS score (C-index = 0.816), STS–EACTS categories (C-index = 0.812), RACHS-1 categories (C-index = 0.802), and Aristotle Basic Complexity scores (C-index = 0.795).

Conclusion: The proposed risk scores and categories have a high degree of discrimination for predicting mortality and represent an improvement over existing consensus-based methods. Risk models incorporating these measures may be used to compare mortality outcomes across institutions with differing case mixes.
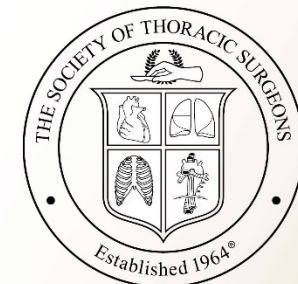
From Subjective Probability to Objective Data

STAT Mortality Score

The **S**ociety of **T**horacic Surgeons - European **A**ssociation for Cardio-**T**horacic Surgery Congenital Heart Surgery Mortality Score

and

STAT Mortality Categories

The **S**ociety of **T**horacic Surgeons - European **A**ssociation for Cardio-**T**horacic Surgery Congenital Heart Surgery Mortality Categories

O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro CP, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L , Peterson ED, Mavroudis C, Edwards FH. **An empirically based tool for analyzing mortality associated with congenital heart surgery**. The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5), November 2009.

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

O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro CP, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L , Peterson ED, Mavroudis C, Edwards FH. **An empirically based tool for analyzing mortality associated with congenital heart surgery.** The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5), November 2009.

STAT Mortality Categories

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

O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro CP, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L , Peterson ED, Mavroudis C, Edwards FH. **An empirically based tool for analyzing mortality associated with congenital heart surgery.** The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5), November 2009.

STAT Mortality Categories

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

- **minimize within-category variation**

and

- **maximize between-category variation**

O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro CP, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L , Peterson ED, Mavroudis C, Edwards FH. **An empirically based tool for analyzing mortality associated with congenital heart surgery.** The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5), November 2009.

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

STAT Category	1	2	3	4	5
■ % Mortality	0.78	2.1	3.4	8.5	19.9

■ % Mortality
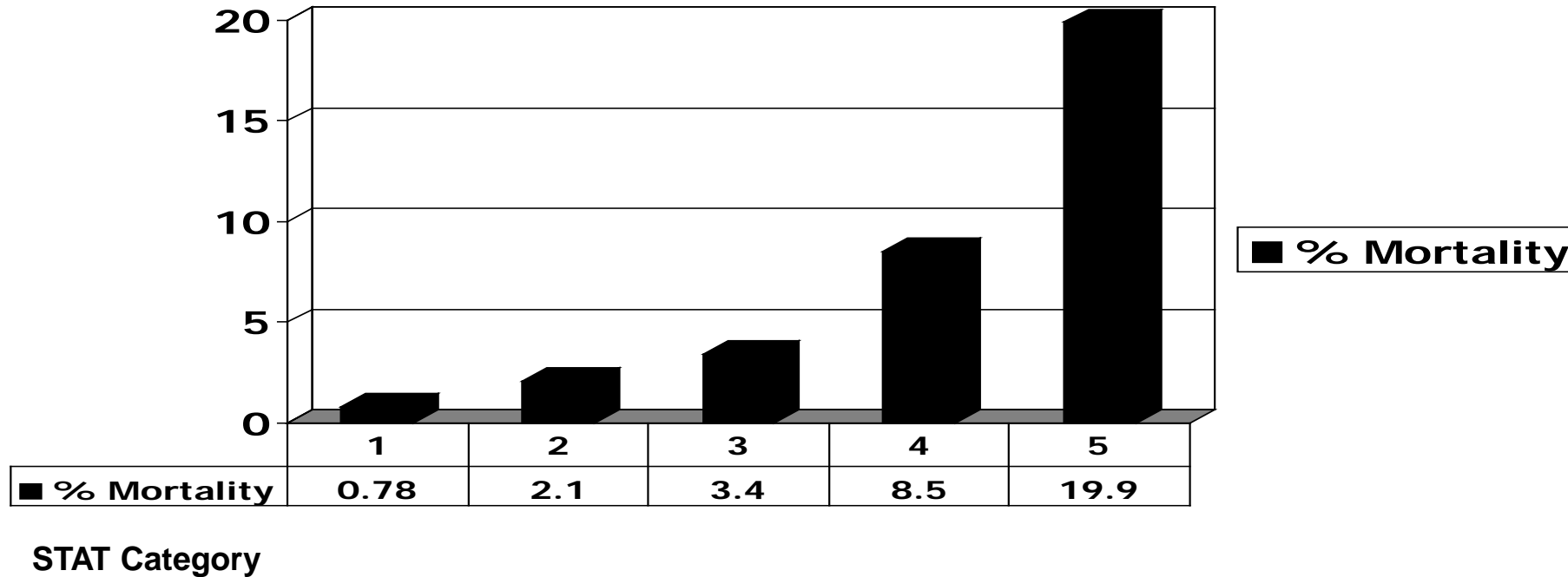
Jacobs JP, Jacobs ML, Maruszewski B, Lacour-Gayet FG, Tchervenkov CI, Tobota Z, Stellin G, Kurosawa H, Murakami A, Gaynor JW, Pasquali SK, Clarke DR, Austin EH 3rd, Mavroudis C. **Initial application in the EACTS and STS Congenital Heart Surgery Databases of an empirically derived methodology of complexity adjustment to evaluate surgical case mix and results**. Eur J Cardiothorac Surg. 2012 Nov;42(5):775-80. doi: 10.1093/ejcts/ezs026. Epub 2012 Jun 14. PMID: 22700597.

An empirically based tool for analyzing morbidity associated with operations for congenital heart disease

Marshall L. Jacobs, MD,[a] Sean M. O'Brien, PhD,[b] Jeffrey P. Jacobs, MD,[c] Constantine Mavroudis, MD,[d] Francois Lacour-Gayet, MD,[e] Sara K. Pasquali, MD,[f] Karl Welke, MD,[g] Christian Pizarro, MD,[h] Felix Tsai, MD,[i] and David R. Clarke, MD[j]

3

Objective: Congenital heart surgery outcomes analysis requires reliable methods of estimating the risk of adverse outcomes. Contemporary methods focus primarily on mortality or rely on expert opinion to estimate morbidity associated with different procedures. We created an objective, empirically based index that reflects statistically estimated risk of morbidity by procedure.

Methods: Morbidity risk was estimated using data from 62,851 operations in the Society of Thoracic Surgeons Congenital Heart Surgery Database (2002-2008). Model-based estimates with 95% Bayesian credible intervals were calculated for each procedure's average risk of major complications and average postoperative length of stay. These 2 measures were combined into a composite morbidity score. A total of 140 procedures were assigned scores ranging from 0.1 to 5.0 and sorted into 5 relatively homogeneous categories.

Results: Model-estimated risk of major complications ranged from 1.0% for simple procedures to 38.2% for truncus arteriosus with interrupted aortic arch repair. Procedure-specific estimates of average postoperative length of stay ranged from 2.9 days for simple procedures to 42.6 days for a combined atrial switch and Rastelli operation. Spearman rank correlation between raw rates of major complication and average postoperative length of stay was 0.82 in procedures with n greater than 200. Rate of major complications ranged from 3.2% in category 1 to 30.0% in category 5. Aggregate average postoperative length of stay ranged from 6.3 days in category 1 to 34.0 days in category 5.

Conclusions: Complication rates and postoperative length of stay provide related but not redundant information about morbidity. The Morbidity Scores and Categories provide an objective assessment of risk associated with operations for congenital heart disease, which should facilitate comparison of outcomes across cohorts with differing case mixes. (J Thorac Cardiovasc Surg 2013;145:1046-57)
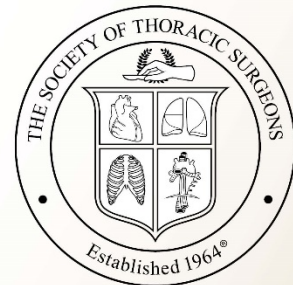
STAT Morbidity Categories

STS Morbidity Score and Categories
were developed based on analysis of **62,851 operations**
entered in the STS Congenital Heart Surgery Databases

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.

STAT Morbidity Categories

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

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.

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STAT Morbidity Categories

- Model-based estimates with 95% Bayesian credible intervals were calculated for each procedure's **average risk of major complications** and **average postoperative length of stay**.

- These 2 measures were combined into a **composite morbidity score**.

- A total of **140 procedures** were assigned scores ranging from **0.1 to 5.0** and sorted into 5 relatively homogeneous categories.

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.
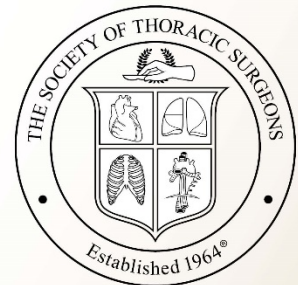
STAT Morbidity Categories

Composite Morbidity

The overall composite morbidity of the j-th procedure was defined as follows:

$$\theta_j = \frac{\pi_j}{s_\pi} + \frac{\mu_j}{s_\mu}$$

where

$$s_\pi = \sqrt{\frac{1}{148} \sum_{j=1}^{148} \left(\pi_j - \frac{1}{148} \sum_{h=1}^{148} \pi_h \right)^2} \quad \text{and}$$

$$s_\mu = \sqrt{\frac{1}{148} \sum_{j=1}^{148} \left(\mu_j - \frac{1}{148} \sum_{h=1}^{148} \mu_h \right)^2}.$$
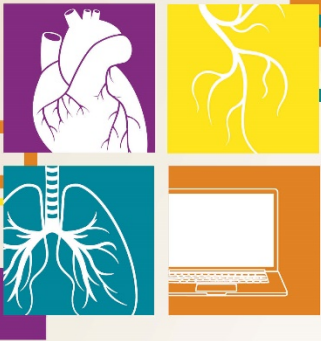
STAT Morbidity Categories

TABLE 2. Major complications

Complication description (STS code*)	No. (%) of events†	Mortality N (%)	Rank correlation with "major complication"
Postoperative acute renal failure requiring temporary or permanent dialysis (220 or 230)	705 (1.1%)	396 (56.2%)	0.59
Postoperative neurologic deficit *persisting at discharge* (320)	500 (0.8%)	152 (30.4%)	0.45
Postoperative AV block requiring permanent pacemaker (60)	593 (0.9%)	28 (4.7%)	0.37
Postoperative mechanical circulatory support (IABP, VAD, ECMO, or CPS) (40)	1110 (1.8%)	617 (55.6%)	0.54
Phrenic nerve injury/paralyzed diaphragm (300)	578 (0.9%)	35 (6.1%)	0.40
Unplanned reoperation (20 or 240)	2942 (4.7%)	636 (21.6%)	0.79
Major complication (defined as any 1 or more of the above)	5059 (8.0%)	1187 (23.5%)	N/A

STS, Society of Thoracic Surgeons; *AV*, atrioventricular; *IABP*, intra-aortic balloon pump; *VAD*, ventricular assist device; *ECMO*, extracorporeal membrane oxygenation; *CPS*, cardiopulmonary support. *Complication codes in the STSCHSD Data Collection Form, Version 2.50.[18] †Denominator is 62,851 operations.

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.
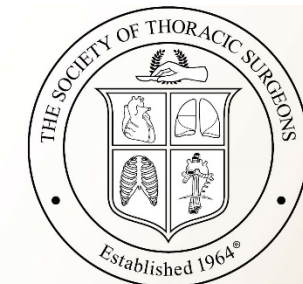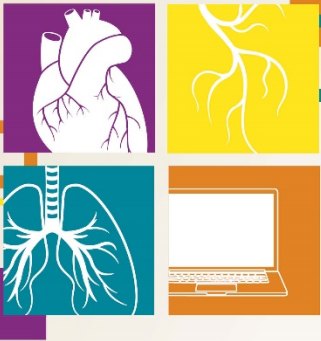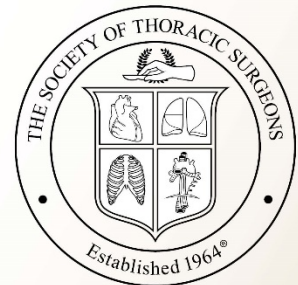
STAT Morbidity Categories

- Individual elements of the complication end point were considered on the basis of their **potential impact on patients' health status**, including durable, long-lasting effects.

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.

STAT Morbidity Categories

- Individual elements of the complication end point were considered on the basis of their potential impact on patients' health status, including **durable, long-lasting effects**.

- We acknowledge that validated **data** describing relationships between some individual complications and late health status are **not readily available**.

Jacobs ML, O'Brien SM, Jacobs JP, Mavroudis C, Lacour-Gayet F, Pasquali SK, Welke K, Pizarro C, Tsai F, Clarke DR. **An empirically based tool for analyzing morbidity associated with operations for congenital heart disease**. J Thorac Cardiovasc Surg. 2013 Apr;145(4):1046-1057.e1. doi: 10.1016/j.jtcvs.2012.06.029. Epub 2012 Jul 24. PMID: 22835225.
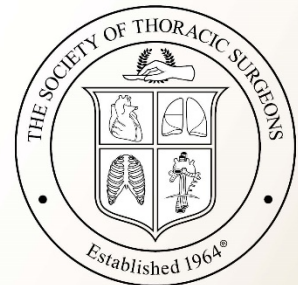
Development of a Congenital Heart Surgery Composite Quality Metric: Part 1—Conceptual Framework

Check for updates

Sara K. Pasquali, MD, MHS, David M. Shahian, MD, Sean M. O'Brien, PhD, Marshall L. Jacobs, MD, J. William Gaynor, MD, Jennifer C. Romano, MD, Michael G. Gaies, MD, MPH, Kevin D. Hill, MD, MS, John E. Mayer, MD, and Jeffrey P. Jacobs, MD

Department of Pediatrics, University of Michigan C.S. Mott Children's Hospital, Ann Arbor, Michigan; Department of Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts; Duke Clinical Research Institute, Duke University School of Medicine, Durham, North Carolina; Division of Cardiac Surgery, Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland; Division of Cardiovascular Surgery, Department of Surgery, Johns Hopkins All Children's Heart Institute, St. Petersburg, Florida; Department of Surgery, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania; Department of Cardiac Surgery, University of Michigan Medical School, Ann Arbor, Michigan; and Department of Cardiovascular Surgery, Boston Children's Hospital, Boston, Massachusetts

Background. Current pediatric and congenital heart surgery quality measures focus on operative mortality, and numerous stakeholders are interested in more comprehensive measures. This report describes the background, rationale, and conceptual framework related to the development of the first composite quality metric in the field.

Methods. A multidisciplinary panel reviewed methodology and framework related to quality measurement and several composite quality measures across adult cardiac surgery and other fields. The panel subsequently developed methodology and selected measures for a congenital heart surgery composite measure and reviewed potential advantages and limitations. Individual measures considered for potential inclusion in the composite were reviewed within the context of Donabedian's triad and the Institute of Medicine quality domains. Decisions were made through group consensus.

Results. The final composite measure selected is comprised of two domains: (1) a mortality domain (operative mortality) and (2) a morbidity domain (the 6 major complications endorsed by The Society of Thoracic Surgeons and Congenital Heart Surgeons Society plus cardiac arrest, and postoperative length of stay). Potential advantages include the more comprehensive view of quality compared with mortality alone and improvements in discrimination of hospital performance through increasing the number of end points. Potential limitations include the lack of longer term outcomes and challenges related to case-mix adjustment.

Conclusions. We have applied and adapted conceptual framework and methodology related to composite quality measures across other fields to congenital heart surgery. The composite quality metric created is inclusive of both morbidity and mortality, and expands our view of quality in this patient population.

(Ann Thorac Surg 2019;107:583–9)
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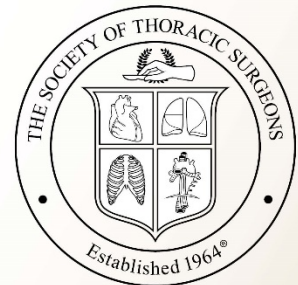
Table 1. STS-CHSD Codes for Complications Included in the Composite Measure

STS-CHSD Code	Complication
230	Renal failure, acute renal failure; acute renal failure requiring dialysis at the time of hospital discharge
223	Renal failure, acute renal failure; acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge
224	Renal failure, acute renal failure; acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge
320	Neurologic deficit; neurologic deficit persisting at discharge
74	Arrhythmia necessitating pacemaker, permanent pacemaker
40	Postoperative/postprocedural mechanical circulatory support
300	Paralyzed diaphragm (possible phrenic nerve injury)
22	Unplanned cardiac reoperation during the postoperative or postprocedural time period, exclusive of reoperation for bleeding
24	Unplanned interventional cardiovascular catheterization procedure during the postoperative or postprocedural time period
26	Unplanned noncardiac reoperation during the postoperative or postprocedural time period
240	Bleeding, requiring reoperation
30	Cardiac arrest, cardiac arrest during or after procedure

STS-CHSD = The Society of Thoracic Surgeons Congenital Heart Surgery Database.

Established 1964®

The Society of Thoracic Surgeons
Congenital Heart Surgery Database
Version 3.41
Updated December 14, 2018

STS National Database™
Using data to drive quality

5

ADMINISTRATIVE

Participant ID: ParticID (10)	Patient Participating in STS-Related Clinical Trial: ClinTrial(81)	☐ None ☐ Trial 1 ☐ Trial 2 ☐ Trial 3 ☐ Trial 4 ☐ Trial 5 ☐ Trial 6
(If not None→)	STS-Related Clinical Trial ID: ClinTrialPatID(82)	

DEMOGRAPHICS

Patient ID (software generated) PatID (520)	Patient Nat. ID (SSN): PatNationalID (110)	MRN: MedRecN (120)
Last Name: PatLName (140)	First Name: PatFName (150)	Middle Name: PatMName (170)
Region: PatRegion (180)	Postal Code: PatPostalCode (190)	Country: PatientCountry (201)

BIRTH INFORMATION

Born by IVF: ☐ Yes ☐ No BornByIVF (202)

Patient Adopted: ☐ Yes ☐ No PatientAdopted (203)

Birth Location Known: ☐ Yes ☐ No BirthLocKnown (208)

| *(If Yes →)*	Born at Home ☐ Yes ☐ No BornHome (209)			
	(If No →)	Birth Hospital Name Known: ☐ Yes ☐ No HospNameKnown (210)		
		(If Yes →)	Birth Hospital Name: BirthHospName (211)	
			Birth Hospital TIN: BirthHospTIN (212)	
	Birth City: BirthCit (219)	Birth Region: BirthSta (220)		Birth CountryBirthCountry (231)
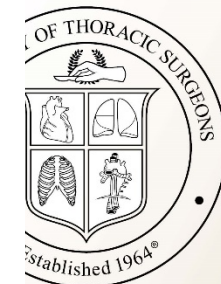
COMPLICATIONS Complication (4200)
Assign complication(s) to the operation that is most closely associated with the complication

☐ 15= No complications   *OR select ALL that apply: (↓)*

☐ 16= No complications during the intraop or postop time periods (No complications prior to discharge & no complications within ≤ 30 days of surgery)

☐ 350= Intraoperative death or intraprocedural death

☐ 360= Unplanned readmission to the hospital within 30 days of surgery or intervention

☐ 370= Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)

☐ 30= Unexpected Cardiac arrest during or following procedure (Periop/Periprocedural = Intraop/Intraprocedural and/or Postop/Postprocedural)

☐ 80= Cardiac dysfunction resulting in low cardiac output

☐ 384= Cardiac failure (severe cardiac dysfunction)

☐ 280= Endocarditis-postprocedural infective endocarditis

☐ 110= Pericardial effusion, Requiring drainage

☐ 390= Pulmonary hypertension

☐ 140= Pulmonary hypertensive crisis (PA pressure > systemic pressure)

☐ 130= Pulmonary vein obstruction

☐ 120= Systemic vein obstruction

☐ 240= Bleeding, Requiring reoperation

☐ 102= Sternum left open, Planned

☐ 104= Sternum left open, Unplanned

☐ 22= Unplanned cardiac reoperation during the postoperative or postprocedural time period, exclusive of reoperation for bleeding

☐ 24= Unplanned interventional cardiovascular catheterization procedure during the postoperative or postprocedural time period

☐ 26= Unplanned non-cardiac reoperation during the postoperative or postprocedural time period

☐ 40= Postoperative/Postprocedural mechanical circulatory support (IABP, VAD, ECMO, or CPS)

☐ 72= Arrhythmia requiring drug therapy
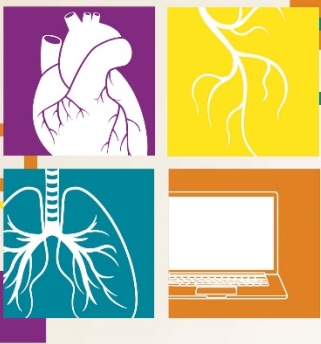
- ☐ 73= Arrhythmia requiring electrical cardioversion or defibrillation
- ☐ 74= Arrhythmia necessitating pacemaker, Permanent pacemaker
- ☐ 75= Arrhythmia necessitating pacemaker, Temporary pacemaker
- ☐ 210= Chylothorax
- ☐ 200= Pleural effusion, Requiring drainage
- ☐ 180= Pneumonia
- ☐ 190= Pneumothorax, Requiring drainage or evacuation
- ☐ 150= Postoperative/Postprocedural respiratory insufficiency requiring mechanical ventilatory support > 7 days
- ☐ 160= Postoperative/Postprocedural respiratory insufficiency requiring reintubation
- ☐ 170= Respiratory failure, Requiring tracheostomy
- ☐ 230= Renal failure - acute renal failure, Acute renal failure requiring dialysis at the time of hospital discharge
- ☐ 223= Renal failure - acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge
- ☐ 224= Renal failure - acute renal failure, Acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge
- ☐ 290= Sepsis
- ☐ 320= Neurological deficit, Neurological deficit persisting at discharge
- ☐ 325= Neurological deficit, Transient neurological deficit not present at discharge
- ☐ 300= Paralyzed diaphragm (possible phrenic nerve injury)
- ☐ 400= Peripheral nerve injury, Neurological deficit persisting at discharge
- ☐ 331= Seizure
- ☐ 410= Spinal cord injury, Neurological deficit persisting at discharge
- ☐ 420= Stroke
- ☐ 440= Subdural Bleed
- ☐ 450= Intraventricular hemorrhage (IVH) > grade 2
- ☐ 470= Thrombus, Intracardiac
- ☐ 480= Thrombus, Central vein
- ☐ 510= Thrombosis/thromboembolism, Pulmonary artery
- ☐ 490= Thrombus, Peripheral deep vein
- ☐ 500= Thrombosis, Systemic to pulmonary shunt
- ☐ 530= Thrombosis, Systemic artery, in situ (central)
- ☐ 540= Thrombosis, Systemic artery, in situ (peripheral)
- ☐ 550= Thrombosis, Systemic artery, embolic
- ☐ 310= Vocal cord dysfunction (possible recurrent laryngeal nerve injury)
- ☐ 250= Wound dehiscence (sterile)
- ☐ 255= Wound dehiscence (sterile), Median sternotomy
- ☐ 520= Sternal instability (sterile)
- ☐ 261= Wound infection
- ☐ 262= Wound infection-Deep wound infection
- ☐ 270= Wound infection-Mediastinitis
- ☐ 263= Wound infection-Superficial wound infection
- ☐ 430= Anesthesia – related complication
- ☐ 460= Complication of cardiovascular catheterization procedure
- ☐ 902= Compartment syndrome
- ☐ 900= Other complication; Specify _____ CompOthSpecify (4201)

- ☐ 901= Other operative/procedural complication; Specify _____
CompOthOpSpecify (4202)
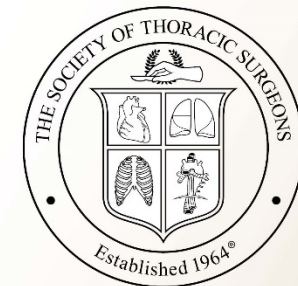
STS Congenital Heart Surgery Database Data Specifications

Version 3.41

This document current as of: 10/14/2018 4:26:59 PM

6

Note: - **ALL fields defined in these specifications with "Core: Yes" are to be collected by all sites.**

- **A data record must be created for each time the patient enters the Operating Room.**

- **Fields indicated with a gray background are no longer being collected.**

STS Congenital Heart Surgery Database   Version 3.41

Long Name:	Participant ID	*SeqNo:*	10
Short Name:	ParticID	*Core:*	Yes
Section Name:	Administrative	*Harvest:*	Yes
DBTableName	Operations		

Definition: Participant ID is a unique number assigned to each database participant by the STS. A database participant is defined as one entity that signs a Participation Agreement with the STS, submits one data file to the harvest, and gets back one report on their data. The participant ID must be entered into each record.

Page 474 out of 591
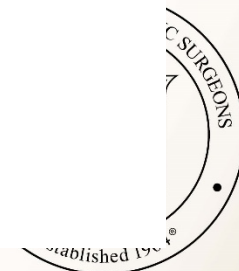
Long Name:	Complications Table Unique Record Identifier	SeqNo:	4180
Short Name:	CompUniqueID	Core:	Yes
Section Name:	Complications	Harvest:	Yes
DBTableName	Complications		
Definition:	Unique identifier for the record in the Complications table.		
Data Source:	Automatic	Format: Text	

Long Name:	Complications Link to Operations Table	SeqNo:	4190
Short Name:	OperationID	Core:	Yes
Section Name:	Complications	Harvest:	Yes
DBTableName	Complications		
Definition:	An arbitrary, unique value generated by the software that permanently identifies each operation record in the participant's database. This field is the foreign key that links the Complications record with the associated record in the Operations table.		
Data Source:	Automatic	Format: Text	

STS Congenital Heart Surgery Database   Version 3.41
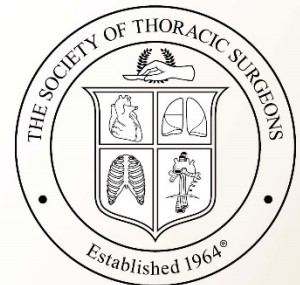
Long Name:	Complication	SeqNo:	4200
Short Name:	Complication	Core:	Yes
Section Name:	Complications	Harvest:	Yes
DBTableName	Complications		

Definition: Assign complication to the operation that is most closely associated with the complication.

A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

An adverse event is a complication that is associated with a healthcare intervention and is associated with suboptimal outcome. Adverse events represent a subset of complications. Not all medical errors result in an adverse event; the administration of an incorrect dose of a medication is a medical error, but it does not always result in an adverse event. Similarly, not all adverse events are the result of medical error. A child may develop pneumonia after an atrial septal defect repair despite intra- and peri-operative management that is free of error. Complications of the underlying disease state, which are not related to a medical intervention, are not adverse events. For example, a patient who presents for medical care with metastatic lung cancer has already developed a complication (Metastatic spread) of the primary lung cancer without any healthcare intervention. Furthermore, complications not associated with suboptimal outcome or harm are not adverse events and are known as no harm events. The patient who receives an incorrect dose of a medication without harm has experienced a no harm event, but not an adverse event.

Data Source: User   Format: Text (categorical values specified by STS)

Harvest Codes and Value Definitions:

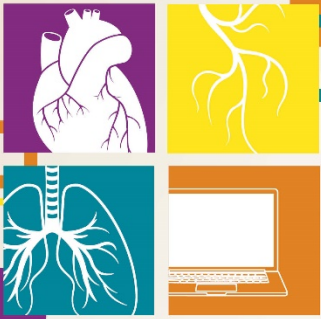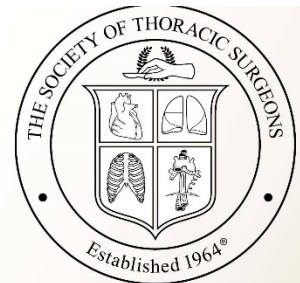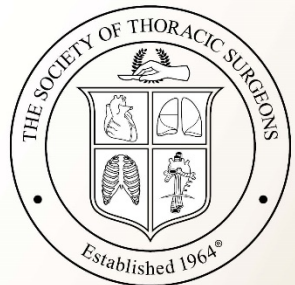| Code:	Value:	Definition:
15	No complications	No complications occurred. A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breach in the standard of care that constitutes medical negligence or medical malpractice.
16	No complications during the intraoperative and postoperative time periods (No complications prior to discharge and no complications within < or = 30 days of surgery)	No intraoperative/intraprocedural or postoperative/postprocedural complication occurred prior to hospital discharge or within < or = 30 days of surgery or intervention. A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breach in the standard of care that constitutes medical negligence or medical malpractice.
350	Intraoperative death or	Patient died in the operating room or procedure room (such as

Definition: Assign complication to the operation that is most closely associated with the complication.

A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of event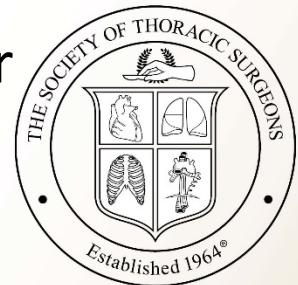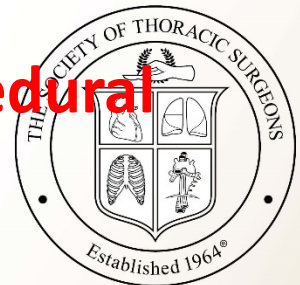s, and may cause, or be associated with, suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice. An operative or procedural complication is any complication, regardless of cause, occurring (1) within 30 days after surgery or intervention in or out of the hospital, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. Operative and procedural complications include both intraoperative/intraprocedural complications and postoperative/postprocedural complications in this time interval.

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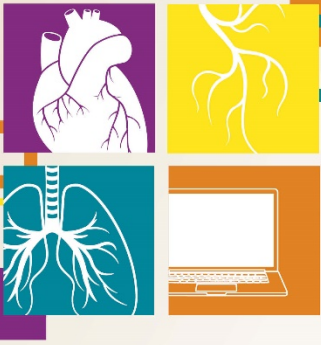
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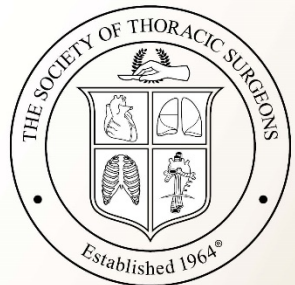# Complication

- A complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome.

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What is an **intraoperative/intraprocedural complication** and what is part of the routine of cardiac surgery?

7

CONGENITAL·HEART·SURGERY·
DATABASE·TRAINING·
MANUAL¶

V3.41¶

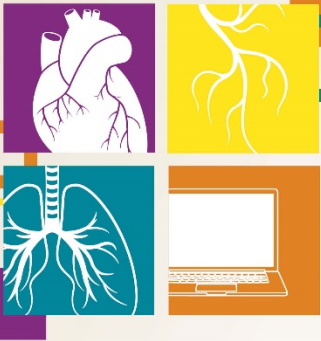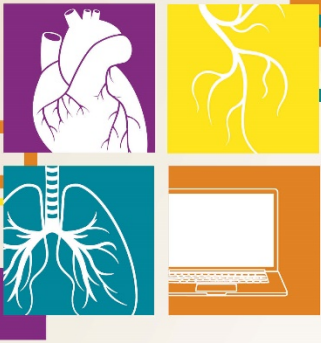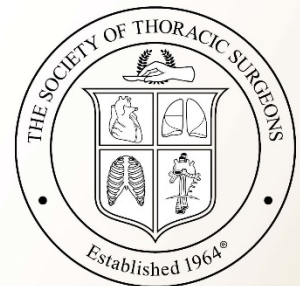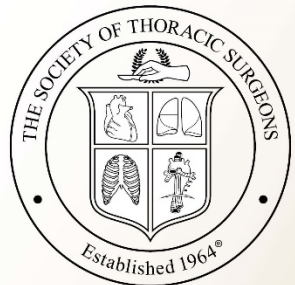| 40 | Postoperative/Postprocedural mechanical circulatory support (IABP, VAD, ECMO, or CPS) | Utilization of postoperative/postprocedural mechanical support, of any type (IABP, VAD, ECMO, or CPS), for resuscitation/CPR or support, during the postoperative/postprocedural time period. Code this complication if it occurs (1) within 30 days after surgery or intervention regardless of the date of hospital discharge, or (2) after 30 days during the same hospitalization subsequent to the operation or intervention. |
72	Arrhythmia requiring drug therapy	Arrhythmia (ROOT Definition) + An arrhythmia requiring drug therapy. Does not include electrolyte replacement, please also code if antiarrhythmic used during cardiac arrest. Do not code this complication for the use of drugs to treat arrhythmias that occur in the process of separating or preparing to separate from cardiopulmonary bypass but resolve prior to leaving the operating theatre.
73	Arrhythmia requiring electrical cardioversion or defibrillation	Arrhythmia (ROOT Definition) + An arrhythmia requiring electrical cardioversion or defibrillation. Please code if defibrillation performed during cardiac arrest. Do not code this complication for the use of cardioversion or defibrillation in the process of separating or preparing to separate from cardiopulmonary bypass.
74	Arrhythmia necessitating pacemaker, Permanent pacemaker	Implantation and utilization of a permanent pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block).
75	Arrhythmia necessitating pacemaker, Temporary pacemaker	Implantation and utilization of a temporary pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block). Please also code if temporary pacemaker used during cardiac arrest. Do not code this complication if the need for temporary pacing is no longer present by the time the patient leaves the operating theatre.

subsequent to the operation or intervention.

72   Arrhythmia requiring drug therapy

Arrhythmia (ROOT Definition) + An arrhythmia requiring drug therapy.   Does not include electrolyte replacement, please also code if antiarrhythmic used during cardiac arrest. Do not code this complication for the use of drugs to treat arrhythmias that occur in the process of separating or preparing to separate from cardiopulmonary bypass but resolve prior to leaving the operating theatre.

| 73 | Arrhythmia requiring electrical cardioversion or defibrillation | Arrhythmia (ROOT Definition) + An arrhythmia requiring electrical cardioversion or defibrillation.   Please code if defibrillation performed during cardiac arrest.   Do not code this complication for the use of cardioversion or defibrillation in the process of separating or preparing to separate from cardiopulmonary bypass. |

75   Arrhythmia necessitating pacemaker,
      Temporary pacemaker

Implantation and utilization of a temporarypacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block).   Please also code if temporary pacemaker used during cardiac arrest.   Do not code this complication if the need for temporary pacing is no longer present by the time the patient leaves the operating theatre.

What is an **intraoperative/intraprocedural complication** and what is part of the routine of cardiac surgery?

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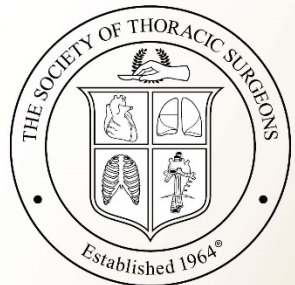
WE NEED RULES

What is an **intraoperative/intraprocedural complication** and what is part of the routine of cardiac surgery?

RULES
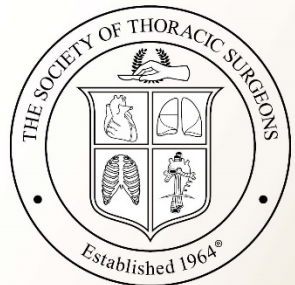
RULES

1. **Arrhythmia necessitating pacemaker, Temporary pacemaker**

2. **Arrhythmia requiring drug therapy**

3. **Arrhythmia requiring electrical cardioversion or defibrillation**

4. **Unexpected cardiac arrest, Timing = Cardiac arrest (MI) during or following procedure (Perioperative/Periprocedural = Intraoperative/Intraprocedural and/or Postoperative/Postprocedural)**

RULES

1. **Arrhythmia necessitating pacemaker, Temporary pacemaker**

Do not code this complication if the need for temporary pacing is no longer present by the time the patient leaves the operating theatre.

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RULES

1. **Arrhythmia necessitating pacemaker, Temporary pacemaker**

Do not code this complication if the need for temporary pacing is no longer present by the time the patient leaves the operating theatre.

2. **Arrhythmia requiring drug therapy**

Do not code this complication if the patient is in the operating theatre and the arterial cannula is connected to the patient.

3. **Arrhythmia requiring electrical cardioversion or defibrillation**

4. **Unexpected cardiac arrest, Timing = Cardiac arrest (MI) during or following procedure (Perioperative/Periprocedural = Intraoperative/Intraprocedural and/or Postoperative/Postprocedural)**

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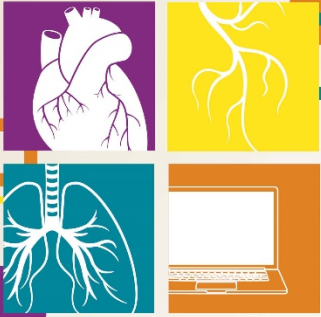
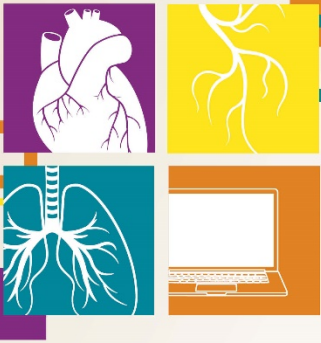# Therefore, the following scenarios are NOT coded as complications:
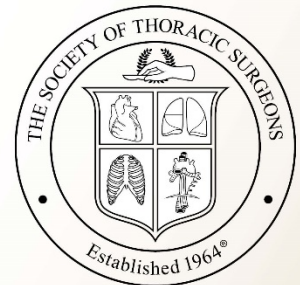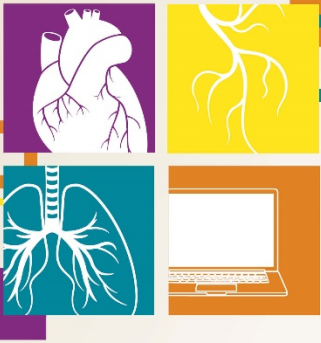
Therefore, the following scenarios are NOT coded as complications:

1. A patient who
   - required temporary pacing after weaning from cardiopulmonary bypass
   - subsequently returned to normal sinus rhythm prior to leaving the OR and
   - was not paced when leaving the OR.

Therefore, the following scenarios are NOT coded as complications:

1. A patient who
   - required temporary pacing after weaning from cardiopulmonary bypass
   - subsequently returned to normal sinus rhythm prior to leaving the OR and
   - was not paced when leaving the OR.

2. A patient who required cardioversion or defibrillation following removal of the aortic cross-clamp removal, during CPB support.
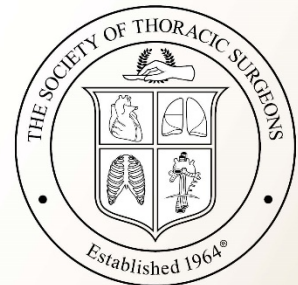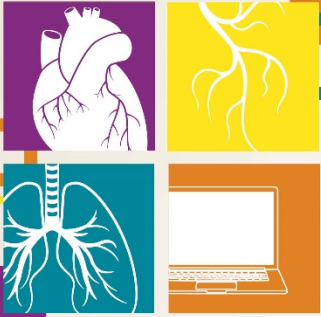
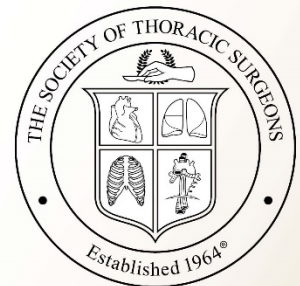# Intraoperative Complications – Defining the Fields

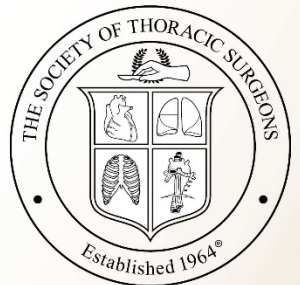Jeffrey P. Jacobs, MD
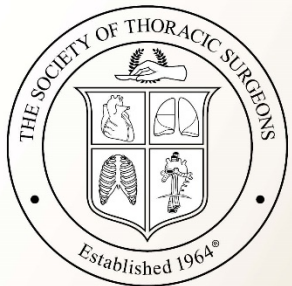
Minor Data Requests

How often do complications happen?

Minor Data Requests - example

"I am interested in writing a paper about Complete repair of Truncus Arteriosus in patients who weigh less than 2000 grams?"

How often does this happen?

Complete repair of Truncus Arteriosus

Weight at Surgery	Number of index cardiac operations	Operative Mortality
All Patients		
All patients less than 2.500 grams		
All patients less than 2,000 grams		
All patients less than 1,800 grams		
All patients less than 1,500 grams		
All patients less than 1,000 grams		

Specifications: Surgery between January 1, 2011 and December 31, 2015

Complete repair of Truncus Arteriosus

Weight at Surgery	Number of index cardiac operations	Operative Mortality
All Patients	773	73 / 772 (9.5%)
All patients less than 2.500 grams	108	14 / 108 (13.0%)
All patients less than 2,000 grams	24	7 / 24 (29.2%)
All patients less than 1,800 grams	15	4 / 15 (26.7%)
All patients less than 1,500 grams	4	1 / 4 (25.0%)
All patients less than 1,000 grams	1	0 / 1 (0.0%)

Specifications: Surgery between January 1, 2011 and December 31, 2015

Complete repair of Truncus Arteriosus with Valvuloplasty of truncal valve or Valvuloplasty of aortic valve

Weight at Surgery	Number of index cardiac operations	Operative Mortality
All Patients		
All patients less than 2.500 grams		
All patients less than 2,000 grams		
All patients less than 1,800 grams		
All patients less than 1,500 grams		
All patients less than 1,000 grams		

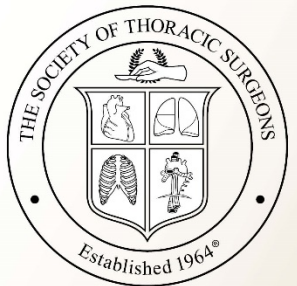Specifications: Surgery between January 1, 2011 and December 31, 2015

Complete repair of Truncus Arteriosus with Valvuloplasty of truncal valve or Valvuloplasty of aortic valve

Weight at Surgery	Number of index cardiac operations	Operative Mortality
All Patients	66	10 / 66 (15.2%)
All patients less than 2.500 grams	8	2 / 8 (25.0%)
All patients less than 2,000 grams	1	1 / 1 (100.0%)
All patients less than 1,800 grams	1	1 / 1 (100.0%)
All patients less than 1,500 grams	NA	NA
All patients less than 1,000 grams	NA	NA

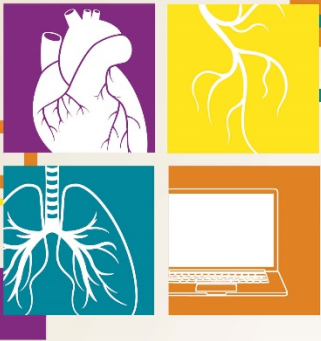Specifications: Surgery between January 1, 2011 and December 31, 2015
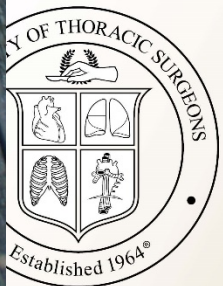
ADVANCES IN QUALITY & OUTCOMES:
A Data Managers Meeting

The Society of Thoracic Surgeons Advances in Quality & Outcomes Conference (Formerly known as the Data Managers Meeting), Marriott Minneapolis City Center, Minneapolis, Minnesota, November 1, 2007.

Intraoperative Complications – Defining the Fields

Jeffrey P. Jacobs, MD