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Introduction

Introduction – Databases and the assessment of complications associated with the treatment of patients with congenital cardiac disease

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Abstract The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease was established in 2005 with the goal of providing the *infrastructure, spanning geographical and subspecialty boundaries, for collaboration between health care professionals* interested in the analysis of outcomes of treatments provided to patients with congenital cardiac disease, with the ultimate aim of improvement in the quality of care provided to these patients. The purpose of these collaborative efforts is to promote the highest quality comprehensive cardiac care to all patients with congenital heart disease, from the fetus to the adult, regardless of the patient's economic means, with an emphasis on excellence in teaching, research and community service. This manuscript provides the Introduction to the 2008 Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease". This Supplement was prepared by The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease.

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease offers the following definition of the term "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."

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease offers the following definition of the term "Adverse Event": "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

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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."

Based on the above definitions, it is apparent that The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has taken an inclusive approach to defining the universe of complications. Complications may or may not be associated with healthcare intervention and may or may not be associated with suboptimal outcome. Meanwhile, adverse events must be associated with healthcare intervention and must be associated with suboptimal outcome.

Keywords: Congenital heart disease; outcomes; complexity; patient safety; complications; surgical outcomes; registry; database; patient safety; cardiac surgery; results of treatment

This Supplement is based on the following Basic Principles: (1) In 2008, mortality prior to discharge from the hospital after congenital and paediatric cardiac surgery is approximately 4% overall in Europe and North America. In order to assess better the quality of care involving the remaining 96% of patients, we must agree on universally accepted definitions of morbidity and complications. (2) Not all complications are caused by medical error and not all medical error results in complications. (3) Not all complications are medical negligence or medical malpractice. (4) Many subtypes of complications exist. (5) The application of the definitions of complications into registries and databases requires certain basic rules. The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons previously have published rules for the assessment of mortality and morbidity and this Supplement builds upon the foundation of these two publications.

This Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease" includes 29 manuscripts and both a Long List of Complications and a Short List of Complications, with consensus-based definitions provided in each List. Therefore, in this Supplement, we provide a Long List of Complications and a Short List of Complications: (1) The Long List of Complications presented in Part IV of this Supplement contains and defines 2836 terms and is named: "*The Long List of Complications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease*", with the abbreviated short name: "*Multi-Societal Long List of Complications*". (2) The Short List of Complications presented in Table 11 of this manuscript contains and defines 56 terms. This Short List of Complications in Table 11 provides the latest version of the *Short List of Complications prepared for The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons*. This version is a draft work in progress that was developed by updating the current version 2.50 Short List of Complications of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, so that the new Short List of Complications shown in Table 11 is consistent and harmonized with the Multi-Societal Long List of Complications published in Part IV of this Supplement.

Acknowledgements

Although the acknowledgements section of a manuscript is usually at the end of the manuscript, I would like to begin this article with the acknowledgments because of their extreme importance. This Supplement truly represents a multi-institutional and multi-disciplinary collaborative effort involving numerous participants. Therefore, prior to beginning this Introductory Manuscript to this Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease", I would like to begin by thanking the following sponsors of this Supplement (Table 1):

- The Children's Heart Foundation (http://www.childrensheartfoundation.org/)
- The Society of Thoracic Surgeons (http://www.sts.org/)
- The VPS, LLC (The Virtual Pediatric Intensive Care Unit Systems, Limited Liability Company) (http://www.myvps.org)
- The World Society for Pediatric and Congenital Heart Surgery (http://www.wspchs.org/)

The Children's Heart Foundation provided US$100,000 to support this research initiative and fund the publication of this Supplement. The Society

of Thoracic Surgeons funded the meetings of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease in 2007 and 2008. The VPS, LLC (The Virtual Pediatric Intensive Care Unit Systems, Limited Liability Company) funded the meetings of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease in 2005 and 2006. The World Society for Pediatric and Congenital Heart Surgery provided US$25,000 towards the publication of this Supplement.

Table 2 lists the recipients of the research Grant from The Children's Heart Foundation titled: "Congenital Heart Disease Multi-Societal Database Project to Create a Universal Encyclopedia for Definitions of Preoperative Risk Factors and Postoperative Complications Related to Congenital Heart Surgery and Interventions". This Supplement addresses the portion of this Grant related to Complications; the portion of the Grant related to Preoperative and Preprocedural Factors is currently in progress and undergoing ongoing investigation.

In addition to funding the meetings of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease in 2007 and 2008, The Society of Thoracic Surgeons provided important administrative support for this initiative. I would like to thank *Fred H. Edwards, MD*, for his outstanding leadership as Chair of the Database Workforce of The Society of Thoracic Surgeons; it has been a true pleasure for me to Chair the Congenital Heart Surgery Database Taskforce of The Society of Thoracic Surgeons under the leadership of Fred. I would also like to thank *Cynthia Shewan*, *Linda Breen*, and *Amy Dancisak* for their massive efforts and crucial administrative support for this initiative.

I would also like to acknowledge *Thomas B. Rice, MD* and *Randall C. Wetzel, MD*, and their colleagues at The VPS, LLC (The Virtual Pediatric Intensive Care Unit Systems, Limited Liability Company). The leadership provided by Tom and Randall is responsible for the creation of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease.

It is very important to acknowledge that the idea to produce this Supplement originally came from *Tjark Ebels, M.D., Ph.D., FECTS*, of Groningen University Medical Centre, Groningen, The Netherlands. Tjark told me by e-mail that in order for surgeons truly to evaluate and compare morbidity and complications, we must create a universal "Dictionary of Complications" associated with the treatment of patients with congenital cardiac disease. It was this e-mail from my good friend Tjark that inspired this research initiative and culminated in the publication of this Supplement.

Part IV of this Supplement provides "The Dictionary of Definitions of Complications associated with the Treatment of Patients with Congenital Cardiac Disease". As we developed the Long List of Complications that appears in Part IV of this Supplement, *Emile Antoine Bacha, MD*, a member of the Editorial Board of this Supplement, agreed to merge a list of Complications generated from work done by Emile and colleagues during their research into intraoperative complications, with the Long List of Complications utilized by The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons. I offer special thanks to Emile and his colleagues for all of their support and hard work to facilitate this project.

I would like to thank the Editorial Board of this Supplement (Table 3), all of whom spent many hours supporting the production of this Supplement. I would like to especially acknowledge the hours of work and effort contributed by *Marshall Lewis Jacobs, MD, Bohdan Maruszewski, MD,* and *Henry L. Walters III, MD* as members of the Executive Editorial Committee. Marshall, Bohdan, and Hal all played a major leadership role in the creation of this Supplement. Without their efforts, the creation of this publication would not have been possible.

Table 4 lists the various organizations and Societies whose members have participated in the meetings and activities of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease and Table 5 lists the various participants themselves. I would like to thank each of these participants listed in Table 5 for their support and help in the completion of this Supplement, and I apologize if I have inadvertently and mistakenly left anyone off this list.

I would like to thank *Constantine (Gus) Mavroudis, MD*, *Francois G. Lacour-Gayet, MD*, and *Martin J. Elliott, MD* for their leadership over the last 15 years in the science of the analysis of outcomes of surgical intervention for congenital cardiac disease. Clearly, all of the accomplishments published in this Supplement stand on the shoulders of the initial efforts of Gus, Francois, and Martin.

Each of the multiple authors that contributed to this Supplement took valuable time away from their personal and professional lives in order to contribute to this initiative. I place high value on the support that this effort received from all of these authors. I also place high value on the sacrifices made by the professional colleagues and family members of these authors in order to create time for these authors to think and write.

I would like to thank Ted Baker, Bob Anderson, Gil Wernovsky, and the team at Cardiology in the

Young, for their support, and for the opportunity to publish this Supplement. On a personal note, I would like to congratulate Bob for his ability to remain massively involved in the academic world of professionals caring for patients with congenitally malformed hearts, even after his official "retirement". I would again like to thank Bob for his support, friendship, mentorship, professional guidance, and advice over the past 11 years. Bob has played a major role in the development of my own career, and I am appreciative for all that he has done for me. He placed an amazingly high level of trust in me when I was very young, and I appreciate this support.

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- Janet Kreutzer, of The Congenital Heart Institute of Florida, Children's Hospital of Tampa, and the University of South Florida, Saint Petersburg and Tampa, Florida, United States of America,
- Jean Wilhelm Kas Sheehan, Diane Krasnopero, Jennifer Carapellucci, and Kristin Rosenberg of The Congenital Heart Institute of Florida, All Children's Hospital, and the University of South Florida, Saint Petersburg and Tampa, Florida, United States of America.
- Melanie Gevitz and Karen Graham of Children's Memorial Hospital, Northwestern University Feinberg School of Medicine, Chicago, Illinois, United States of America

Finally, I would like to thank my current partners, Jim Quintessenza and Paul Chai, and, and my former partners, Victor Morell and Harald Lindberg, for their constant support and guidance, and my wife Stacy, and children Jessica and Joshua, for their understanding and patience. It continues to be an ongoing fact, as I have emphasized in previous Supplements to Cardiology in the Young, that all of the family members of the authors of the reviews included in this Supplement are owed a debt of gratitude, because writing manuscripts markedly decreases the time available with them. Unfortunately, even with the passage of time, these periods of writing and editing are showing no signs of disappearance.

Background

In 2000, a landmark publication from the Institute of Medicine (IOM) estimated that as many as 98,000 people die in any given year from medical errors that occur in hospitals. The following text is taken directly from this report:[1]

> "Health care is not as safe as it should be. A substantial body of evidence points to medical errors as a leading cause of death and injury.
>
> - Sizable numbers of Americans are harmed as a result of medical errors. Two studies of large samples of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, found that the proportion of hospital admissions experiencing an adverse event, defined as injuries caused by medical management, were 2.9 and 3.7 percent,[2] respectively. The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah.[3]
> - Preventable adverse events are a leading cause of death in the United States. When extrapolated to the over 33.6 million admissions to US hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.[4] Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death.[5] Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).[6]"

The Institute of Medicine report has generated significant interest in the evaluation of the quality of medical care. The public, our patients, insurance companies, and the government, all desire transparent disclosure of the outcomes of medical and surgical treatments. In the United States of America, this concept is best exemplified by The National Quality Forum. Table 6 presents the Mission Statement, Vision Statement, and Strategic Goals of The National Quality Forum of the United States of America. The following text is taken directly from the web site of The National Quality Forum[7]:

> "The National Quality Forum (NQF) is a not-for-profit membership organization created to develop and implement a national strategy for health care quality measurement and reporting. A shared sense of urgency about the impact of health care quality on patient outcomes, workforce productivity, and health care costs prompted leaders in the public and private sectors to create the NQF as a mechanism to bring about national change.
>
> Established as a public-private partnership, the NQF has broad participation from all parts of the health care system, including national, state, regional, and local groups representing consumers, public and private purchasers, employers, health care professionals, provider organizations, health plans, accrediting bodies, labor unions, supporting industries, and organizations involved in health care research or quality improvement. Together, the organizational members of the NQF will work to promote a common approach to measuring health care quality and fostering system-wide capacity for quality improvement."

Part of the responsibility of being a professional is self-regulating the profession, taking measures to improve the state of the art in this profession, and in the process, "raising the bar".[8,9] John Edmund Mayer, Jr, the immediate past President of The Society of Thoracic Surgeons, has emphasized the importance of professional responsibility and accountability.[10,11] These professional responsibilities of self-regulation, as well as maintenance and propagation of a body of knowledge, are fundamental. Sir William Osler stated:[12,13]

> "You are in this profession as a calling, not as a business; as a calling which exacts from you at every turn self-sacrifice, devotion, love and tenderness to your fellowmen. Once you get down to a purely business level, your influence is gone and the true light of your life is dimmed. You must work in the missionary spirit, with a breadth of charity that raises you far above the petty jealousies of life."

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Over the past five decades, tremendous progress had been made in the diagnosis and treatment of patients with congenital cardiac malformations. Survival is now expected for many patients with lesions previously considered untreatable. Mortality is a necessary, but insufficient, definition of outcome. As mortality ceases to be effective as a primary measure of outcome, and as new, frequently non-surgical, treatments emerge, new indicators are needed to describe the results of treatments for patients with congenitally malformed hearts. Description of outcomes requires true multidisciplinary involvement, and should include input from surgeons, cardiologists, anaesthesiologists, intensivists, perfusionists, neurologists, educators, primary care physicians, nurses, physician assistants, ultrasonographers, physical therapists, patients, families, governmental representatives, and all other interested parties.[14–25]

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease was established in 2005 with the goal of providing the *infrastructure, spanning geographical and subspecialty boundaries, for collaboration between health care professionals* interested in the analysis of outcomes of treatments provided to patients with congenital cardiac disease, with the ultimate aim of improvement in the quality of care provided to these patients. The purpose of these collaborative efforts is to promote the highest quality comprehensive cardiac care to all patients with congenital heart disease, from the fetus to the adult, regardless of the patient's economic means, with an emphasis on excellence in teaching, research and community service. This 2008 Supplement to Cardiology in the Young that you are about to read is a product of the efforts of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, which in this Introductory manuscript will be occasionally referred to as the Multi-Societal Database Committee.

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has held four annual retreats, each lasting two days, in 2005, 2006, 2007, and 2008:

1. The First Annual Meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease. Chicago, Illinois, Chicago Hilton, Thursday August 25, 2005 and Friday August 26, 2005. (At the inception of this first meeting, the meeting was named the "VPS/STS/PCICS Combined Database Meeting". VPS=The Virtual Pediatric Intensive Care Unit Systems, STS=The Society of Thoracic Surgeons, PCICS=The Pediatric Cardiac Intensive Care Society.)
2. The Second Annual Meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease. Chicago, Illinois, Thursday August 17, 2006 and Friday, August 18, 2006.
3. The Third Annual Meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease. Hotel George in Washington, DC, Thursday September 27, 2007 and Friday, September 28, 2007.
4. The Fourth Annual Meeting of The Multi-Societal Database Committee for Pediatric and

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Congenital Heart Disease. Omni Mount-Royal Hotel, Montreal, Canada, Saturday October 4, 2008 and Sunday October 5, 2008.

Table 4 lists the various organizations and Societies whose members have participated in the meetings and activities of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease and Table 5 lists the various participants themselves. I would like to thank each of these participants listed in Table 5 for their support and help in the completion of this Supplement, and I apologize if I have inadvertently and mistakenly left anyone off this list.

At the first meeting of the Multi-Societal Database Committee, initial discussions took place about the possibility of linking together the various databases of the subspecialties of paediatric cardiac surgery, paediatric cardiology, paediatric cardiac anaesthesia, and paediatric critical care. The Multi-Societal Database Committee rapidly realized that it would be essential to collaborate in multiple areas:

- Use of a common language and *nomenclature*
- Use of a *database* with an established uniform core dataset for collection of information
- Incorporation of a mechanism of evaluating case *complexity*
- Availability of a mechanism to assure *verification* of the completeness and accuracy of the data collected
- *Collaboration* between medical and surgical subspecialties,
- Standardization of protocols for life-long *longitudinal follow-up*.

Each of these six areas is discussed in detail in this Supplement. Initial discussions of the Multi-Societal Database Committee identified that it was essential for the various subspecialty databases to use identical nomenclature in order to allow them to communicate with each other with meaning. Various lists of terminology would need to be harmonized:

- Diagnoses
- Procedures
- Complications
- Preoperative Factors

The Multi-Societal Database Committee agreed to use The International Pediatric and Congenital Cardiac Code (IPCCC) (http://www.ipccc.net/) as the basis of communication. Mature and well developed Short Lists and Long Lists of Diagnoses and Procedures are available via The International Pediatric and Congenital Cardiac Code, and these diagnostic and procedural lists have been incorporated into the various subspecialty databases and harmonized. For example, the *Short Lists of Diagnoses and Procedures of the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons* (Tables 7 and 8) is now used in the following databases:

- The Congenital Heart Surgery Database of The Society of Thoracic Surgeons
- The Congenital Heart Surgery Database of The European Association for Cardio-Thoracic Surgery
- The "IMPACT", (IMproving Pediatric and Adult Congenital Treatment) Database of Congenital Cardiology of The American College of Cardiology
- The Congenital Heart Disease Database of The Congenital Cardiac Anesthesia Society
- The Virtual Pediatric Intensive Care Unit Systems, utilized by members of The Pediatric Cardiac Intensive Care Society

Because the diagnostic and procedural lists in The International Pediatric and Congenital Cardiac Code are matured and functional, the Multi-Societal Database Committee adopted these lists and harmonized them across their databases. The Multi-Societal Database Committee then elected to focus on developing a mature list of Complications and defining these complications. After completing the initiative related to Complications, which is the focus of this Supplement, the Multi-Societal Database Committee then plans to focus on Preoperative Factors. The project dealing with Preoperative Factors will follow the publication of this Supplement. The term "Preoperative Factors" will be used, rather than the term "Preoperative Risk Factors", because, as pointed out by Marshall Jacobs: We do not yet know if these factors are all associated with risk; indeed, the purpose of studying these factors is to determine if they are associated with risk.

Finally, the Multi-Societal Database Committee for Pediatric and Congenital Heart Disease realizes that, ultimately, in order to link the various databases of our subspecialties, each database must incorporate a shared set of Unique Patient Identifier Fields compliant with the Health Insurance Portability and Accountability Act (HIPAA) of the federal government of the United States of America. Efforts are ongoing to incorporate these shared Unique Patient Identifier Fields into all of the various databases of our subspecialties.[25]

Complications

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease offers the following definition of the term "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."

The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease offers the following definition of the term "Adverse Event":

> "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."

Based on the above definitions, it is apparent that The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has taken an inclusive approach to defining the universe of complications. Complications may or may not be associated with healthcare intervention and may or may not be associated with suboptimal outcome. Meanwhile, adverse events must be associated with healthcare intervention and must be associated with suboptimal outcome.

This Supplement is based on the following Basic Principles:

1. In 2008, mortality prior to discharge from the hospital after congenital and paediatric cardiac surgery is approximately 4% overall in Europe and North America. In order to assess better the quality of care involving the remaining 96% of patients, we must agree on universally accepted definitions of morbidity and complications.
2. Not all complications are caused by medical error and not all medical error results in complications.
3. Not all complications are medical negligence or medical malpractice.
4. Many subtypes of complications exist.
5. The application of the definitions of complications into registries and databases requires certain basic rules. The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons previously have published rules for the assessment of mortality and morbidity in the following manuscripts (Tables 9 and 10). This Supplement builds upon the foundation of these two publications:[21,22]

Jacobs JP, Mavroudis C Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. *What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee*. Ann Thorac Surg 2006; 81: 1937–1941.

Jacobs JP, Jacobs ML, Mavroudis C, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ, Vener DF, Barach P, Benavidez OJ, Bacha EA. *What is Operative Morbidity? Defining Complications in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee*. Ann Thorac Surg 2007; 84: 1416–1421.

The Difference between a Short List and a Long List

Obviously, a Short List is short and a Long List is long. Each type of list is designed to serve a different purpose. A Long List is designed to support research studies, academic databases, echocardiography software, and electronic medical records. A Short List is designed to support registries, the assessment of outcomes, and initiatives designed to improve quality.

In this Supplement, we provide a Long List of Complications and a Short List of Complications,

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with consensus-based definitions provided in each List:

- The Long List of Complications presented in Part IV of this Supplement contains and defines 2836 terms and is named: "*The Long List of Complications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease*", with the abbreviated short name: "*Multi-Societal Long List of Complications*". Although the act of navigating a list with 2836 terms can initially seem quite daunting, it can become quite simple and enjoyable with the aid of computerized navigation tools designed to support the hierarchal structure of the list.
- The Short List of Complications presented as Table 11 of this manuscript contains and defines 56 terms. This Short List of Complications in Table 11 provides the latest version of the *Short List of Complications prepared for The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons*. This version is a draft work in progress that was developed by updating the current version 2.50 Short List of Complications of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, so that the new Short List of Complications shown in Table 11 is consistent and harmonized with the Multi-Societal Long List of Complications published in Part IV of this Supplement.

The Organizational Structure of this Supplement: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease"

This Supplement is divided into four parts. Part I is an Overview and contains 3 manuscripts:

- This Introductory Manuscript that you are now reading
- An updated primer about Nomenclature and Databases that functions as a summary of this entire Supplement presented as a single manuscript
- A manuscript that discusses the importance of the globalization of these efforts, written by the Governing Council of The World Society for Pediatric and Congenital Heart Surgery, one of the sponsors of this Supplement

Part II addresses Databases, Complications, and Morbidity and is divided into five sections:

- Nomenclature
- Database
- Stratification of complexity and other biostatistical topics
- Verification of data
- Longitudinal follow-up

Part III discusses "organ specific complications" and has individual chapters discussing complications related to each of the following "organ systems":

- Cardiac complications
- Arrhythmic complications
- Complications relating to perfusion and extracorporeal circulation
- Pulmonary complications
- Renal complications
- Haematological and infectious complications
- Neurological complications
- Gastrointestinal complications
- Congenital cardiac surgical complications of the integument, vascular system, vascular-line(s), and wounds
- Endocrinal complications
- Complications related to the transplantation of thoracic organs
- Anesthetic complications

Part IV of this Supplement provides "The Dictionary of Definitions of Complications associated with the Treatment of Patients with Congenital Cardiac Disease". The Dictionary in Part IV has two components. Table 1 in Part IV provides the list of 43 "Organ Systems" by which the 2836 terms in Table 2 in Part IV are organized. In Table 2 in Part IV, each of these 2836 terms is assigned to an "organ system", listed, defined, and given alphanumeric codes in both The International Pediatric and Congenital Cardiac Code and the 9th revision of the International Classification of Diseases.

The Process of Peer Review and Creating the Long List of Complications

The process of peer review and creating this Long List of Complications is described in detail below:

1. In 2000, an initial Long List of Complications was created based on The International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons published in the Supplement to The Annals of Thoracic Surgery in April 2000.
2. In 2005, this Long List of Complications was merged with a similar list generated from work done by Emile Bacha and colleagues during their research into intraoperative complications. I offer special thanks to Emile and his colleagues for all of their support and hard work to facilitate this project.

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3. Also in 2005, the first annual meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease was held in Chicago, Illinois, at the Chicago Hilton on Thursday August 25, 2005 and Friday August 26, 2005. (At the inception of this first meeting, the meeting was named the "VPS/STS/PCICS Combined Database Meeting". VPS=The Virtual Pediatric Intensive Care Unit Systems, STS=The Society of Thoracic Surgeons, PCICS=The Pediatric Cardiac Intensive Care Society.) The Multi-Societal Database Committee agreed to take on the task of creating a comprehensive listing of complications and defining these complications.
4. In 2005, the product of steps 1 and 2 above was a new Long List of Complications. This new list was then divided into 7 portions broken down by "Organ Systems". Each portion was then assigned to a multidisciplinary subcommittee of the The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease.
5. The Subcommittees studied, reviewed, and modified their terms and definitions and presented updated versions at the 2006 meeting of the Congenital Heart Surgery Database Taskforce of The Society of Thoracic Surgeons at the 2006 meeting of the The American Association for Thoracic Surgery (AATS) in Philadelphia. At this meeting in Philadelphia, each Subcommittee presented their controversial and challenging areas and topics and also presented potential areas of overlap with other Subcommittees.
6. Based on the discussion at the 2006 meeting of the Congenital Heart Surgery Database Taskforce of The Society of Thoracic Surgeons in Philadelphia, each Subcommittee then further researched and revised their lists and definitions.
7. Hal Walters and I then combined the revised lists from the Subcommittees, rectified any remaining inconsistencies in definition or classification between Subcommittees, fused these 7 portions back into one list, and assigned the appropriate codes from the 9th revision of the International Classification of Diseases (ICD-9 Codes) and the appropriate cross-mapped terms from the Short List of Complications of the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons. Rodney Franklin then assigned appropriate alphanumeric codes from The International Pediatric and Congenital Cardiac Code. I would like especially to thank Hal Walters and Rodney Franklin who spent many, many, many, hours on this task. This work would not have been possible without the efforts of Hal and Rodney.
8. These definitions were reviewed again in Chicago, Illinois during the second annual meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease held in Chicago on Thursday August 17, 2006 and Friday, August 18, 2006. Terms and definitions were extensively debated and modified at this meeting in order to build consensus.
9. These definitions were reviewed again in San Diego at the 2007 meeting of the Congenital Heart Surgery Database Taskforce of The Society of Thoracic Surgeons at the 2006 meeting of The Society of Thoracic Surgeons in Philadelphia on Saturday January 27, 2007. Again, terms and definitions were extensively debated and modified at this meeting in order to build consensus.
10. These definitions were reviewed again in Washington, DC on Saturday May 5, 2007 at the 2007 meeting of the Congenital Heart Surgery Database Taskforce of The Society of Thoracic Surgeons at the 2007 meeting of the The American Association for Thoracic Surgery (AATS). Again, terms and definitions were extensively debated and modified at this meeting in order to build consensus.
11. Final review of the terms and definitions presented in Part IV of this Supplement took place at the third annual meeting of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease at Hotel George in Washington, DC on Thursday September 27, 2007 and Friday, September 28, 2007.
12. Hal Walters then confirmed and updated the assignment of appropriate alphanumeric codes from the 9th revision of the International Classification of Diseases ICD-9 Code. Rodney Franklin then confirmed and updated the assignment of appropriate alphanumeric codes from The International Pediatric and Congenital Cardiac Code. Again, I would like especially to thank Hal Walters and Rodney Franklin who spent many, many, many, hours on this task. This work would not have been possible without the efforts of Hal and Rodney.
13. The remaining manuscripts in Parts I, II, and III were written by members of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease. Each manuscript was peer reviewed by a minimum of 2 members

of the Multi-Societal Database Committee who were not authors on that particular manuscript.

14. The above efforts culminated in this publication of this Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease", which includes 29 manuscripts and both a Long List of Complications and a Short List of Complications, with consensus-based definitions provided in each List. Therefore, in this Supplement, we provide a Long List of Complications and a Short List of Complications: (1) The Long List of Complications presented in Part IV of this Supplement contains and defines 2836 terms and is named: "*The Long List of Complications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease*", with the abbreviated short name: "*Multi-Societal Long List of Complications*". (2) The Short List of Complications presented in Table 11 of this manuscript contains and defines 56 terms. This Short List of Complications in Table 11 provides the latest version of the *Short List of Complications prepared for The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons*. This version is a draft work in progress that was developed by updating the current version 2.50 Short List of Complications of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, so that the new Short List of Complications shown in Table 11 is consistent and harmonized with the Multi-Societal Long List of Complications published in Part IV of this Supplement.

Future Directions

The Multi-Societal Long List of Complications and the associated definitions provided in Part IV of this Supplement, and in reality, all of the material published in this Supplement, represent a work in evolution. In essence, this Supplement provides a snap shot of the current state of the art of Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease, as of October, 2008. The terms in the dictionary and the associated definitions are in continuous evolution and will continue to develop and mature. This Supplement, and especially Part IV of this Supplement, is a fluid document that represents a work in progress. For example, in the "Organ System" titled "Cardiopulmonary bypass and Mechanical support", five main groups of complications exist and are defined:

- Cardiopulmonary bypass complication
- ECMO complication
- IABP complication
- VAD complication
- VAD complication-INTERMACS Registry

(ECMO = extracorporeal membrane oxygenation, IABP = intra-aortic balloon pump, VAD = ventricular assist device) This section of the Multi-Societal Long List of Complications demonstrates that this document is still a "work-in progress". The first four groups of complications in the list above were prepared by the Multi-Societal Database Committee working in collaboration with The International Consortium for Evidence-Based Perfusion (http://www.bestpracticeperfusion.org/). The fifth group of complications in the list above is taken from the INTERMACS Registry (http://www.intermacs.org/). The International Consortium for Evidence-Based Perfusion and the INTERMACS Registry are described below in quotes taken directly from their own websites on October 13, 2008:

> "The International Consortium for Evidence-Based Perfusion (ICEBP) partners and collaborates with perfusion societies, professional medical societies, interested clinicians and industry to improve continuously the delivery of care and outcomes for our patients.
>
> *Vision of the ICEBP*
>
> To achieve this mission, we will:
>
> - Evaluate current practice through a dedicated international perfusion registry.
> - Develop and publish evidence based guidelines, and support their integration into clinical practice.
> - Identify gaps in the medical literature and empower clinical teams to conduct research in areas where evidence is lacking.
> - Identify gaps between current and evidence-based clinical practice to promote the improvement in patient care."

> "INTERMACS is a national registry for patients who are receiving mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives in conjunction with the University of Alabama at Birmingham (UAB) and United Network for Organ Sharing (UNOS). "

This example demonstrates that the Multi-Societal Long List of Complications is truly still a

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"work-in progress". The list of Complications in the "Organ System" titled "Cardiopulmonary bypass and Mechanical support" still will require further work so that the portion of the list prepared by the Multi-Societal Database Committee working in collaboration with The International Consortium for Evidence-Based Perfusion can be fully harmonized with the portion of the list incorporated from the INTERMACS Registry. Clearly, this Dictionary is a living, breathing document that will continue to evolve.

Future goals and initiatives of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease include the following projects and initiatives:

1. Providing the *infrastructure, spanning geographical and subspecialty boundaries, for collaboration between health care professionals* interested in the analysis of outcomes of treatments provided to patients with congenital cardiac disease, with the ultimate aim of improvement in the quality of care provided to these patients
2. Maintaining, preserving, and updating the *Long List of Complications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease*
3. Developing and defining a similar *List of Preoperative and Preprocedural Factors*
4. Studying the relationship between *clinical and administrative databases*
5. Incorporating into our Database a shared set of *Unique Patient Identifier Fields* compliant with the Health Insurance Portability and Accountability Act of the United States of America, and all other related local, national, and international governmental regulations.
6. Developing additional strategies to *link our Databases*
7. Creating standardized strategies for *longitudinal follow-up* of our patients
8. Assuring that all of these efforts *span subspecialty boundaries*
9. Assuring that all of these efforts *span geographic boundaries* by improving the *Globalization* of efforts of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease.

Europe and North America are very well represented in these efforts. Increasing the involvement from Africa, Asia, Australia and Oceania, and South America, is of extreme importance. The geographical boundaries of our efforts must be expanded. To date, unfortunately, meetings of the MultiSocietal Database Committee have been held only in North America. Meetings must be held in other continents, mimicking the efforts of The International Society for Nomenclature of Paediatric and Congenital Heart Disease, developers of the International Paediatric and Congenital Cardiac Code. The International Society for Nomenclature of Paediatric and Congenital Heart Disease has met in Argentina, Brazil, Canada, Italy, Japan, the United States of America, and Poland. The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease must mimic this globalized approach exemplified by The International Society for Nomenclature of Paediatric and Congenital Heart Disease. The analysis of outcomes of treatments provided to patients with congenital cardiac disease, and the improvement in the quality of care provided to these patients, is truly a global challenge and responsibility.

In the final analysis, The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease has devoted a great deal of energy to the international collaborative efforts to standardize the assessment of outcomes of patients undergoing treatment for congenital cardiac disease. I feel strongly that this international collaboration MUST span traditional geographic and subspecialty boundaries. In this way, we, as congenital cardiac surgeons, physicians, and health care professionals, will not only improve our profession and the lives of our patients—we will also foster global collaboration and understanding, and therefore improve the world.

References

1. Kohn LT, Corrigan JM, Donaldson M (eds). Committee on Quality of Health Care in America, Institute of Medicine (IOM) Report – To Err Is Human: Building a Safer Health System. National Academy of Sciences, Washington, DC, 2000. (Free Executive Summary). [http://www.nap.edu/catalog/9728.html], accessed October 11, 2007.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. N Engl J Med 1991; 324: 370–376; **See also**: Leape LL, Brennan TA, Laird NM, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med 1991; 324: 377–384. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care forthcoming Spring 2000.
3. Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of Medical Injuries in Utah and Colorado. Inquiry 1999; 36: 255–264; See also: Leape, et al., 1991; Brennan, et al., 1991.
4. American Hospital Association. Hospital Statistics. Chicago. 1999.
5. Centers for Disease Control and Prevention (National Center for Health Statistics). Deaths: Final Data for 1997. National Vital Statistics Reports 1999; 47: 27.
6. Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. National Vital Statistics Reports 1999; 47: 6.
7. [http://www.qualityforum.org/], accessed October 12, 2008.
8. Jacobs JP. Caring for Patients with Congenital Cardiac Disease – Introduction to Part 6 of the Supplement. Cardiol Young 2005; 15 (Suppl 1): 159–160.

https://doi.org/10.1017/S104795110800334X Published online by Cambridge University Press

9. Cohen M, Jacobs JP, Quintessenza JA, et al. Mentorship, learning curves and balance. Cardiol Young 2007; 17 (Suppl 2): 164–174; doi: 10.1017/S1047951107001266.
10. Bonchek LI, Harley DP, Wilbur RH, et al. The STS future planning conference for adult cardiac surgery. Ann Thorac Surg 2003; 76: 2156–2166.
11. Mayer JE . Threats to the Medical Profession by the American Medicare System. Presented as a Visiting Professor at the Ninth Annual Anthony RC Dobell Day in Congenital Cardiac Surgery, Montreal Children's Hospital and McGill University, Montreal, Canada, Monday, December 4, 2006.
12. The Reserves of Life.St. Mary's Hosp Gaz 1907; 13: 95–98.
13. [http://www.acponline.org/college/pressroom/osler_feat.htm], accessed October 11, 2007.
14. Jacobs JP, Franklin RCG, Jacobs ML, et al. Classification of the functionally univentricular heart: Unity from mapped codes. Cardiol Young 2006; 16 (Suppl 1): 9–21.
15. Tchervenkov CI, Jacobs JP, Weinberg PM, et al. The nomenclature, definition and classification of hypoplastic left heart syndrome. Cardiol Young 2006; 16: 339–368.
16. Jacobs JP, Franklin RCG, Wilkinson JL, et al. The nomenclature, definition and classification of discordant atrioventricular connections. Cardiol Young 2006; 16 (Suppl 3): 72–84.
17. Jacobs JP, Anderson RH, Weinberg P, et al. The nomenclature, definition and classification of cardiac structures in the setting of heterotaxy. Cardiol Young 2007; 17 (Suppl 2): 1–28; doi: 10.1017/S1047951107001138, September 2007.
18. Jacobs JP, Mavroudis C, Jacobs ML, et al. Lessons learned from the data analysis of the Second Harvest (1998–2001) of The Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database. Eur J Cardiothorac Surg 2004; 26: 18–37.
19. Jacobs JP, Lacour-Gayet FG, Jacobs ML, et al. Initial application in the STS congenital database of complexity adjustment to evaluate surgical case mix and results. Ann Thorac Surg 2005; 79: 1635–1649.
20. Jacobs JP, Jacobs ML, Maruszewski B, et al. Current status of the European Association for Cardio-Thoracic Surgery and the Society of Thoracic Surgeons Congenital Heart Surgery Database. Ann Thorac Surg 2005; 80: 2278–1183; discussion 2283–2284.
21. Jacobs JP, Mavroudis C, Jacobs ML, et al. What is operative mortality? Defining death in a surgical registry database: a report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee. Ann Thorac Surg 2006; 81: 1937–1941.
22. Jacobs JP, Jacobs ML, Mavroudis C, et al. What is operative morbidity? Defining complications in a surgical registry database: a report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. Ann Thorac Surg 2007; 84: 1416–1421.
23. Jacobs JP, Mavroudis C, Jacobs ML, et al. Nomenclature and databases – the past, the present, and the future: a primer for the congenital heart surgeon. Pediatr Cardiol 2007; 28: 105–115; Epub 2007 May 4, May 2007.
24. Jacobs JP, Wernovsky G, Elliott MJ. Analysis of outcomes for congenital cardiac disease: Can we do better? Cardiol Young 2007; 17 (Suppl 2): 145–158; doi: 10.1017/S1047951107001278, September 2007.
25. Jacobs JP, Haan CK, Edwards FH, et al. The rationale for incorporation of HIPAA compliant unique patient, surgeon, and hospital identifier fields in the STS Database. Ann Thorac Surg 2008; 86: 695–698; doi:10.1016/j.athoracsur.2008.04.075. September, 2008.

Table 1. Sponsorship for the Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease"

Supplement prepared by:
The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Editor:
Jeffrey Phillip Jacobs, MD, FACS, FACC, FCCP

Sponsored by:
The Children's Heart Foundation (http://www.childrensheartfoundation.org/)

and
The Society of Thoracic Surgeons (http://www.sts.org/)

and
The VPS, LLC (The Virtual Pediatric Intensive Care Unit Systems, Limited Liability Company) (http://www.myvps.org)

and
The World Society for Pediatric and Congenital Heart Surgery (http://www.wspchs.org/)

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Table 2. Recipients of the research Grant from The Children's Heart Foundation titled: "Congenital Heart Disease Multi-Societal Database Project to Create a Universal Encyclopedia for Definitions of Preoperative Risk Factors and Postoperative Complications Related to Congenital Heart Surgery and Interventions"

Jeffrey Phillip Jacobs, MD, FACS, FACC, FCCP	Principal Investigator
Marshall Lewis Jacobs, MD	Co-investigator
Henry L. Walters III, MD	Co-investigator
Emile Bacha, MD	Co-investigator
Kathy Jenkins, MD, MPH	Co-investigator
Tina Merola, RN	Research Nurse Coordinator
Debbie McIntosh	Study Coordinator

Table 3. The Editorial Board for the Supplement to Cardiology in the Young titled: "Databases and The Assessment of Complications associated with the Treatment of Patients with Congenital Cardiac Disease"

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Table 4. The 36 organizations and Societies whose members have participated in the meetings and activities of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Cardiac Surgery

1. The Society of Thoracic Surgeons (STS)
2. The Society of Thoracic Surgeons Congenital Database Data Verification Subcommittee
3. The Society of Thoracic Surgeons Congenital Database Taskforce
4. The Society of Thoracic Surgeons Congenital Database Taskforce Core Users Group
5. The American Association for Thoracic Surgery (AATS)
6. The European Association for Cardio-Thoracic Surgery (EACTS)
7. The European Association for Cardio-Thoracic Surgery Congenital Heart Committee
8. Asian Society for Cardiovascular and Thoracic Surgery
9. Japanese Association for Thoracic Surgery
10. Japan Congenital Cardiovascular Surgery Database (JCCVSD)
11. The Congenital Heart Surgeons' Society (CHSS)
12. The European Congenital Heart Surgeons Association (ECHSA) (Formerly The European Congenital Heart Surgeons Foundation [ECHSF])
13. The Southern Thoracic Surgical Association (STSA)
14. The Western Thoracic Surgical Association (WTSA)
15. The World Society for Pediatric and Congenital Heart Surgery
16. Cardiothoracic Surgery Network

Cardiology

17. The American College of Cardiology (ACC)
18. The American Heart Association (AHA)
19. The Association for European Paediatric Cardiology (AEPC)
20. The Joint Council on Congenital Heart Disease (The Joint Council on Congenital Heart Disease [JCCHD] is a council composed of the current chairs of four core organizations related to pediatric cardiology in the United States of America: the sub board of Pediatric Cardiology of the American Board of Pediatrics, the section of Congenital Heart Disease/Pediatric Cardiology of the American College of Cardiology, the Council of Cardiovascular Disease in the Young of the American Heart Association, and the Section of Cardiology and Cardiac Surgery of the American Academy of Pediatrics. In addition, the Joint Council includes representation from the International Society of Adult Congenital Cardiac Disease, the Congenital Heart Surgeon's Society, and the Society of Thoracic Surgery. Originally formed to improve communication between the various groups involved with congenital heart disease and pediatric cardiology, the Joint Council on Congenital Heart Disease meets once a year in the fall to share information between the represented organizations and to help coordinate national activities related to Pediatric Cardiology, Pediatric Cardiac Surgery, and Congenital Heart Disease.)

Anaesthesia

21. The Congenital Cardiac Anesthesia Society

Critical Care

22. The Pediatric Cardiac Intensive Care Society (PCICS)
23. The Virtual Pediatric Intensive Care Unit Systems (VPS), utilized by members of The Pediatric Cardiac Intensive Care Society (PCICS)

Perfusion

24. The Pediatric Committee of the International Consortium of Evidence Based Perfusion

Governmental Organizations

25. The Birth Defect Branch of the Centers for Disease Control and Prevention (CDC) of the United States of America
26. The Center for Quality Improvement and Patient Safety of Agency for Healthcare Research and Quality (AHRQ) of the United States Department of Health and Human Services of the United States of America
27. The Central Cardiac Audit Database of the United Kingdom (CCAD)

Nongovernmental Organizations

28. The Aristotle Institute, developers of the Aristotle Complexity Score
29. The Multi-Center Panel of Experts for Cardiac Surgical Outcomes, developers of the Risk Adjustment in Congenital Heart Surgery-1(RACHS-1) system
30. The National Association of Children's Hospitals and Related Institutions (NACHRI)
31. The Extracorporeal Life Support Organization (ELSO)
32. The Pediatric Heart Transplant Study Group (PHTSG)
33. The International Society for Nomenclature of Paediatric and Congenital Heart Disease
34. The International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Nomenclature Working Group (NWG) of The International Society for Nomenclature of Paediatric and Congenital Heart Disease
35. The International Working Group for Defining the Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Definitions Working Group (DWG) of The International Society for Nomenclature of Paediatric and Congenital Heart Disease
36. The International Working Group for Archiving and Cataloguing the Images and Videos of the Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Archiving Working Group (AWG) of The International Society for Nomenclature of Paediatric and Congenital Heart Disease, and the Congenital Heart Archiving Research Team (CHART)

Table 5. Participants in the meetings and activities of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Subspecialty	Last Name	First Name	Middle Initial or Name	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6
Cardiac Surgery	Al-Halees	Zohair							6
Cardiac Surgery	Bacha	Emile	Antoine			3	4	5	6
Cardiac Surgery	Backer	Carl	L.						6
Cardiac Surgery	Bernier	Pierre-Luc							6
Cardiac Surgery	Caldarone	Christopher	A.						6
Cardiac Surgery	Chai	Paul	J.				4		6
Cardiac Surgery	Cicek	Sertac	M.						6
Cardiac Surgery	Clarke	David	Robinson			3	4	5	6
Cardiac Surgery	Cohen	Gordon	A.						6
Cardiac Surgery	Dabal	Robert							6
Cardiac Surgery	Dearani	Joseph	A.				4		6
Cardiac Surgery	Dodge-Khatami	Ali							6
Cardiac Surgery	Ebels	Tjark							6
Cardiac Surgery	Edwards	Fred	H.			3			6
Cardiac Surgery	Edwards	Fred	H.						6
Cardiac Surgery	Elliott	Martin	J.						6
Cardiac Surgery	Gaynor	J. William							6
Cardiac Surgery	Hickey	Edward	J.					5	6
Cardiac Surgery	Hirsch	Jennifer	Christel						6
Cardiac Surgery	Jacobs	Jeffrey	Phillip	1	2	3		5	6
Cardiac Surgery	Jacobs	Marshall	Lewis		2	3	4	5	6
Cardiac Surgery	Jaggers	James							6
Cardiac Surgery	Jatene	Marcelo	B.						6
Cardiac Surgery	Jonas	Richard	A.						6
Cardiac Surgery	Karamichalis	John							6
Cardiac Surgery	Karamlou	Tara							6
Cardiac Surgery	Kinsley	Robin	H.						6
Cardiac Surgery	Kreutzer	Christian							6
Cardiac Surgery	Kurosawa	Hiromi							6
Cardiac Surgery	Lacour-Gayet	Francois	G.			3	4		6
Cardiac Surgery	Leon-Wyss	Juan							6
Cardiac Surgery	Liu	Jinfen							6
Cardiac Surgery	Manning	Peter							6
Cardiac Surgery	Maruszewski	Bohdan			2	3			6
Cardiac Surgery	Mavroudis	Constantine				3			6
Cardiac Surgery	Morales	David	L.S.					5	6
Cardiac Surgery	Mosca	Ralph							6
Cardiac Surgery	Murakami	Arata							6
Cardiac Surgery	Myers	Jeff							6
Cardiac Surgery	Nunn	Graham	R.						6
Cardiac Surgery	O'Brien	James							6
Cardiac Surgery	Ohye	Richard	G.						6
Cardiac Surgery	Pizarro	Christian							6
Cardiac Surgery	Pourmoghadam	Kamal							6
Cardiac Surgery	Ramirez-Marroquin	Samuel							6
Cardiac Surgery	Ring	Steve							6
Cardiac Surgery	Sandoval	Nestor							6
Cardiac Surgery	Sano	Shunji							6
Cardiac Surgery	Sarris	George	E.						6
Cardiac Surgery	Scholl	Frank							6
Cardiac Surgery	Sharma	Rajesh							6
Cardiac Surgery	Shen	Irving							6
Cardiac Surgery	Shoeb	Ayman							6
Cardiac Surgery	Spray	Thomas	L.						6
Cardiac Surgery	Stellin	Giovanni				3			6
Cardiac Surgery	Tchervenkov	Christo	I.			3		5	6
Cardiac Surgery	Ungerleider	Ross	M.						6
Cardiac Surgery	Walters III	Henry	L.		2	3	4	5	6
Cardiac Surgery	Welke	Karl	F.			3		5	6
Cardiac Surgery	Williams	William	G.						6

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Table 5. *Continued*

Subspecialty	Last Name	First Name	Middle Initial or Name	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6
Cardiac Surgery	Yangni-Angate	Herve′							6
Cardiac Surgery	Yeh Jr	Thomas							6
Cardiac Surgery	Ziemer	Gerhard							6
Cardiac Surgical Research	Diggs	Brian	S.						6
Cardiac Surgical Research	Gevitz	Melanie							6
Cardiac Surgical Research	McClellan	Andrew	J.						6
STS Administration	Breen	Linda	S.						6
Cardiac Surgical Database manager	Merola	Tina							6
Cardiology	Beekman III	Robert	H.						6
Cardiology	Beland	Marie	J.						6
Cardiology	Benavidez	Oscar	J.						6
Cardiology	Bergersen	Lisa							6
Cardiology	Colan	Steven	D.						6
Cardiology	Deal	Barbara	J.					5	6
Cardiology	Dipchand	Anne I.							6
Cardiology	Everett	Allen							6
Cardiology	Forbes	Thomas	J.						6
Cardiology	Franklin	Rodney	C. G.			3		5	6
Cardiology	Giroud	Jorge	M.						6
Cardiology	Jenkins	Kathy	J.			3		5	6
Cardiology	Klitzner	Thomas							6
Cardiology	Krogmann	Otto	N.						6
Cardiology	Martin	Gerard	R.						6
Cardiology	Rosenthal	Geoff							6
Cardiology	Vincent	Robert							6
Cardiology	Webb	Catherine	L.						6
Cardiology	Wilkinson	Jim							6
Cardiology and CDC	Mahle	William	T.						6
Cardiology and Biostatistics	McCrindle	Brian	W.						6
Cardiology and Cardiac Pathology	Aiello	Vera	D.						6
Cardiology and Cardiac Pathology	Weinberg	Paul							6
Cardiac Morphology	Anderson	Robert	H.			3			6
Anaesthesia	Andropoulos	Dean							6
Anaesthesia	Barach	Paul							6
Anesthesia	Harrington	James							6
Anesthesia	Holtby	Helen							6
Anesthesia	Lavoie	Josee							6
Anaesthesia	Schindler	Ehrenfried							6
Anaesthesia	Shukla	Avinash							6
Anaesthesia	Tirotta	Christopher	F.						6
Anaesthesia	Vener	David	F.			3	4	5	6
Critical Care	Bird	Geoffrey	L.				4	5	6
Critical Care	Bronicki	Ronald							6
Critical Care	Chang	Anthony	C.						6
Critical Care	Checchia	Paul	A.				4	5	6
Critical Care	Cooper	David	S.				4	5	6
Critical Care	Dickerson	Heather						5	6
Critical Care	Easterling	Larry							6
Critical Care	Ghanayem	Nancy	S.				4	5	6
Critical Care	Jeffries	Howard	E.				4	5	6
Critical Care	LaRovere	Joan	M.					5	6
Critical Care	Nelson	David	P.						6
Critical Care	Rice	Thomas	B.			3			6
Critical Care	Scanlon	Matt							6
Critical Care	Thiagarajan	Ravi							6
Critical Care	Wernovsky	Gil							6
Critical Care	Wessel	David	L.						6
Critical Care	Wetzel	Randall	C.			3			6

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Table 5. *Continued*

Subspecialty	Last Name	First Name	Middle Initial or Name	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6
VPS—NACHRI	Gorman	Mary							6
VPS—Executive VP & COO National Outcomes Center, VPS, LLC	Sachdeva	Ramesh	C.						6
VPS—NACHRI (Director, VPS)	Sedehi	Lesley							6
Manager National Benchmarking	Gall	Chris							6
Clinical Systems Analyst	Lauer	Casey							6
Nursing	Jacoby	Katie							6
Perfusion	Calaritis	Christos							6
Perfusion	Chancy	Tom							6
Perfusion	Charette	Kevin							6
Perfusion	Giacomuzzi	Carmen	R.						6
Perfusion	Gomez	Daniel							6
Perfusion	Groom	Robert	C.						6
Perfusion	Harness	Lynn							6
Perfusion	Lawson	D. Scott							6
Perfusion	Likosky	Donald	S.						6
Perfusion	McRobb	Craig	M.						6
Perfusion	Mellas	Nicholas							6
Perfusion	Myers	Gerard	J.						6
Perfusion	Ojito	Jorge	W.						6
Perfusion	Parpard	Michael							6
Perfusion	Paugh	Theron	A.						6
Perfusion	Shann	Kenneth	G.					5	6
Perfusion	Thuys	Clarke	A.						6
Perfusion	Tinius-Juliani	Julie							6
Neurology	Licht	Daniel	J.						6
Transplant	Law	Yuk							6
Biostatistics	Gauvreau	Kimberlee							6
Biostatistics	O'Brien	Sean	M.					5	6
Biostatistics and Surgery	Blackstone	Eugene	H.						6
Computer Programmer	Tobota	Zdzislaw							6
CDC	Botto	Lorenzo	D.						6
CDC	Correa	Adolfo							6
CDC	Reller	Mark	D.						6
CDC	Riehle-Colarusso	Tiffany	J.						6
CDC	Strickland	Matthew	J.					5	6
CDC	Tolbert	Paige	E.						6
AHRQ Medical Officer	Gray	Darryl							6

Roles: 1 = Editor, 2 = Executive Editorial Committee, 3 = Editorial Board, 4 = Subcommittee Chair, 5 = First author on manuscript, 6 = Participant in the meetings or activities or publications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease

Legend: AHRQ = Agency for Healthcare Research and Quality (AHRQ) of the United States of America
CDC = Centers for Disease Control and Prevention (CDC) of the United States of America
CDC = Centers for Disease Control and Prevention (CDC) of the United States of America
COO = Chief Operating Officer
NACHRI = The National Association of Children's Hospitals and Related Institutions
STS = The Society of Thoracic Surgeons
VP = Vice President
VPS = Virtual Pediatric Intensive Care Unit Database System

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Table 6. The Mission Statement, Vision Statement, and Strategic Goals of The National Quality Forum (NQF) of the United States of America[7]

Mission Statement:

The mission of the National Quality Forum is to improve the quality of American healthcare by setting national priorities and goals for performance improvement, endorsing national consensus standards for measuring and publicly reporting on performance, and promoting the attainment of national goals through education and outreach programs.

Vision:

- The NQF will be the convener of key public and private sector leaders to establish national priorities and goals to achieve the Institute of Medicine Aims—health care that is safe, effective, patient-centered, timely, efficient and equitable.
- NQF-endorsed standards will be the primary standards used to measure and report on the quality and efficiency of healthcare in the United States.
- The NQF will be recognized as a major driving force for and facilitator of continuous quality improvement of American healthcare quality.

Strategic Goals:

1. Establish an ongoing structure for convening public and private sector leaders to set (and periodically update) National Priorities and Goals for performance improvement of the US health care system.
2. Develop a Performance Measurement Framework that will assure the availability of a comprehensive set of NQF-endorsed performance measures adequate to evaluate progress in meeting national goals for each of the priority areas and to satisfy the information needs of multiple stakeholders, including consumers, purchasers, providers, health plans and policy makers.
   a. Identify gaps in currently available NQF-endorsed measures
   b. Attempt to fill gaps by issuing a "call for measures" and identifying the best measures that satisfy NQF criteria.
   c. Where adequate measures do not currently exist, encourage measure developers to fill such gaps.
3. Strengthen and streamline the NQF Measure Endorsement and Maintenance Processes
   a. Implement the recommendations of the Ad Hoc CDP Committee
   b. Establish a mechanism to promote ongoing communication and collaboration between measure developers and NQF to promote "measure harmonization," facilitate composite measure development, and ensure that NQF-endorsed measures have specifications that facilitate incorporation into EHRs.
   c. Work with stewards of NQF-endorsed measures to implement measure maintenance processes that are "real time" and transparent.
4. Sponsor Education and Outreach Initiatives to encourage and facilitate achievement of meaningful and sustainable advances in the quality of care.
   a. Enhance communication with NQF Members and opportunities for Member involvement
      i. Implement new membership council/issue group structure
      ii. Take greater advantage of web-based and other methods of information dissemination and communication with Members.
      iii. Enhance and expand participation in NQF National Policy Conference on Quality and the Annual and Membership Meetings.
   b. Develop a Quality Resource Center
      i. Build a web-based resource center to help leaders navigate the fast-moving quality environment, tracking issues such as national goal setting efforts, use of standardized measures, payment innovations, and state and national public reporting initiatives, and providing a vehicle for stakeholder feedback to refine strategies to drive improvement.
      ii. Continue to expand leadership programs and activities including the Annual Leadership Colloquium and related activities.
   c. Continue sponsorship and enhancement of recognition of programs.
      i. John M. Eisenberg Award for Patient Safety and Quality, co-sponsored with the Joint Commission, recognizes major achievements of individuals and organizations in improving patient safety and quality.
      ii. NQF National Quality Healthcare Award, an annual award recognizing healthcare organizations that demonstrate commitment to transparency and data-driven, whole-system improvement.
5. Contribute to the development of an effective and efficient National Quality Measurement and Reporting Infrastructure.
   a. Actively participate and contribute to the work of the Alliance Steering Committee, AQA, CMS, Hospital Quality Alliance, The Joint Commission and NCQA.
   b. Engage in educational and outreach activities to encourage stable and adequate funding for such an infrastructure.

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Table 7. Short List of Diagnoses of the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons

Kingdom	Phylum	Diagnostic Short List Term	STS Harvest Code
Septal Defects	ASD	PFO	10
		ASD, Secundum	20
		ASD, Sinus venosus	30
		ASD, Coronary sinus	40
		ASD, Common atrium (single atrium)	50
	VSD	VSD, Type 1 (Subarterial) (Supracristal) (Conal septal defect) (Infundibular)	71
		VSD, Type 2 (Perimembranous) (Paramembranous) (Conoventricular)	73
		VSD, Type 3 (Inlet) (AV canal type)	75
		VSD, Type 4 (Muscular)	77
		VSD, Type: Gerbode type (LV-RA communication)	79
		VSD, Multiple	80
		VSD + Aortic arch hypoplasia	92
		VSD + Coarctation of aorta	94
	AV Canal	AVC (AVSD), Complete CAVSD	100
		AVC (AVSD), Intermediate (transitional)	110
		AVC (AVSD), Partial (incomplete) (PAVSD) (ASD, primum)	120
	AP Window	AP window (aortopulmonary window)	140
		Pulmonary artery origin from ascending aorta (hemitruncus)	150
	Truncus Arteriosus	Truncus arteriosus	160
		Truncal valve insufficiency	170
Pulmonary Venous Anomalies	Partial Anomalous Pulmonary Venous Connection	Partial anomalous pulmonary venous connection (PAPVC)	180
		Partial anomalous pulmonary venous connection (PAPVC), scimitar	190
	Total Anomalous Pulmonary Venous Connection	Total anomalous pulmonary venous connection (TAPVC), Type 1 (supracardiac)	200
		Total anomalous pulmonary venous connection (TAPVC), Type 2 (cardiac)	210
		Total anomalous pulmonary venous connection (TAPVC), Type 3 (infracardiac)	220
		Total anomalous pulmonary venous connection (TAPVC), Type 4 (mixed)	230
Cor Triatriatum		Cor triatriatum	250
Pulmonary Venous Stenosis		Pulmonary venous stenosis	260
Systemic Venous Anomalies	Anomalous Systemic Venous Connection	Systemic venous anomaly	270
Right Heart Lesions		Systemic venous obstruction	280
	Tetralogy of Fallot	TOF	290
		TOF, AVC (AVSD)	300
		TOF, Absent pulmonary valve	310
	Pulmonary Atresia	Pulmonary atresia	320
		Pulmonary atresia, IVS	330
		Pulmonary atresia, VSD (Including TOF, PA)	340
		Pulmonary atresia, VSD-MAPCA (pseudotruncus)	350
		MAPCA(s) (major aortopulmonary collateral[s]) (without PA-VSD)	360
	Tricuspid Valve Disease and Ebstein's Anomaly	Ebstein's anomaly	370
		Tricuspid regurgitation, non-Ebstein's related	380
		Tricuspid stenosis	390
		Tricuspid regurgitation and tricuspid stenosis	400
		Tricuspid valve, Other	410
	RVOT Obstruction, IVS Pulmonary Stenosis	Pulmonary stenosis, Valvar	420
		Pulmonary artery stenosis (hypoplasia), Main (trunk)	430
		Pulmonary artery stenosis, Branch, Central (within the hilar bifurcation)	440

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Table 7. *Continued*

Kingdom	Phylum	Diagnostic Short List Term	STS Harvest Code
		Pulmonary artery stenosis, Branch, Peripheral (at or beyond the hilar bifurcation)	450
		Pulmonary artery, Discontinuous	470
		Pulmonary stenosis, Subvalvar	490
		DCRV	500
	Pulmonary Valve Disease	Pulmonary valve, Other	510
		Conduit failure	520
		Pulmonary insufficiency	530
	Conduit failure	Pulmonary insufficiency and pulmonary stenosis	540
Left Heart Lesions	Aortic Valve Disease	Aortic stenosis, Subvalvar	550
		Aortic stenosis, Valvar	560
		Aortic stenosis, Supravalvar	570
		Aortic valve atresia	590
		Aortic insufficiency	600
		Aortic insufficiency and aortic stenosis	610
		Aortic valve, Other	620
	Sinus of Valsalva Fistula/Aneurysm	Sinus of Valsalva aneurysm	630
	LV to Aorta Tunnel	LV to aorta tunnel	640
	Mitral Valve Disease	Mitral stenosis, Supravalvar mitral ring	650
		Mitral stenosis, Valvar	660
		Mitral stenosis, Subvalvar	670
		Mitral stenosis, Subvalvar, Parachute	680
		Mitral stenosis	695
		Mitral regurgitation and mitral stenosis	700
		Mitral regurgitation	710
		Mitral valve, Other	720
	Hypoplastic Left Heart Syndrome	Hypoplastic left heart syndrome (HLHS)	730
	Cardiomyopathy	Cardiomyopathy	740
		Cardiomyopathy, End-stage congenital heart disease	750
	Pericardial Disease	Pericardial effusion	760
		Pericarditis	770
		Pericardial disease, Other	780
Single Ventricle		Single ventricle, DILV	790
		Single ventricle, DIRV	800
		Single ventricle, Mitral atresia	810
		Single ventricle, Tricuspid atresia	820
		Single ventricle, Unbalanced AV canal	830
		Single ventricle, Heterotaxia syndrome	840
		Single ventricle, Other	850
Transposition of the Great Arteries	Congenitally Corrected TGA	Congenitally corrected TGA	870
		Congenitally corrected TGA, IVS	872
		Congenitally corrected TGA, IVS-LVOTO	874
		Congenitally corrected TGA, VSD	876
		Congenitally corrected TGA, VSD-LVOTO	878
	Transposition of the Great Arteries	TGA, IVS	880
		TGA, IVS-LVOTO	890
		TGA, VSD	900
		TGA, VSD-LVOTO	910
DORV		DORV, VSD type	930
		DORV, TOF type	940
		DORV, TGA type	950
		DORV, Remote VSD (uncommitted VSD)	960
		DORV, IVS	975
DOLV		DOLV	980
Thoracic Arteries and Veins	Coarctation of Aorta (all types)	Coarctation of aorta	990
		Aortic arch hypoplasia	1000
		Coronary artery anomaly, Anomalous aortic origin	1010
	Coronary Artery Anomalies	Coronary artery anomaly, Anomalous pulmonary origin (includes ALCAPA)	1020
		Coronary artery anomaly, Fistula	1030
		Coronary artery anomaly, Aneurysm	1040

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Table 7. *Continued*

Kingdom	Phylum	Diagnostic Short List Term	STS Harvest Code
		Coronary artery anomaly, Other	1050
	Interrupted Arch	Interrupted aortic arch	1070
	Patent Ductus Arteriosus	Patent ductus arteriosus	1080
	Vascular rings and Slings	Vascular ring	1090
		Pulmonary artery sling	1100
	Aortic Aneurysm	Aortic aneurysm (including pseudoaneurysm)	1110
	Aortic Dissection	Aortic dissection	1120
Lung Disease	Lung Disease	Lung disease, Benign	1130
		Lung disease, Malignant	1140
	Pectus Excavatum, Carinatum	Pectus	1150
	Tracheal Stenosis	Tracheal stenosis	1160
		Airway disease	1170
Electrophysiologic		Arrhythmia	1180
		Arrhythmia, Heart block	1185
		Arrhythmia, Heart block, Acquired	1190
		Arrhythmia, Heart block, Congenital	1200
		Arrhythmia, Pacemaker, Indication for replacement	1220
Miscellaneous, Other		Atrial Isomerism, Left	1230
		Atrial Isomerism, Right	1240
		Aneurysm, Ventricular, Right	1250
		Aneurysm, Ventricular, Left	1260
		Aneurysm, Pulmonary artery	1270
		Aneurysm, Other	1280
		Hypoplastic RV	1290
		Hypoplastic LV	1300
		Mediastinitis	1310
		Endocarditis	1320
		Rheumatic heart disease	1325
		Prosthetic valve failure	1330
		Myocardial infarction	1340
		Cardiac tumor	1350
		Pulmonary AV fistula	1360
		Pulmonary embolism	1370
		Pulmonary vascular obstructive disease	1385
		Pulmonary vascular obstructive disease (Eisenmenger's)	1390
		Primary pulmonary hypertension	1400
		Persistent fetal circulation	1410
		Meconium aspiration	1420
		Pleural disease, Benign	1430
		Pleural disease, Malignant	1440
		Pneumothorax	1450
		Pleural effusion	1460
		Chylothorax	1470
		Empyema	1480
		Esophageal disease, Benign	1490
		Esophageal disease, Malignant	1500
		Mediastinal disease	1505
		Mediastinal disease, Benign	1510
		Mediastinal disease, Malignant	1520
		Diaphragm paralysis	1540
		Diaphragm disease, Other	1550
		Cardiac, Other	1560
		Thoracic and/or mediastinal, Other	1570
		Peripheral vascular, Other	1580
		Status post transplant, Heart	1590
		Status post transplant, Lung	1600
		Status post transplant, Heart and lung	1610
		Normal heart	7000
		Miscellaneous, Other	7777

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Table 8. Short List of Procedures of the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the International Congenital Heart Surgery Nomenclature and Database Project of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons

Kingdom	Phylum	Procedural Short List Term	STS Harvest Code
Septal Defects	ASD	PFO, Primary closure	10
		ASD repair, Primary closure	20
		ASD repair, Patch	30
		ASD repair, Device	40
		ASD, Common atrium (single atrium), Septation	50
		ASD creation/enlargement	60
		ASD partial closure	70
		Atrial septal fenestration	80
		Atrial fenestration closure	85
	VSD	VSD repair, Primary closure	100
		VSD repair, Patch	110
		VSD repair, Device	120
		VSD, Multiple, Repair	130
		VSD creation/enlargement	140
		Ventricular septal fenestration	150
	AV Canal	AVC (AVSD) repair, Complete (CAVSD)	170
		AVC (AVSD) repair, Intermediate (Transitional)	180
		AVC (AVSD) repair, Partial (Incomplete) (PAVSD)	190
	AP Window	AP window repair	210
		Pulmonary artery origin from ascending aorta (hemitruncus) repair	220
	Truncus Arteriosus	Truncus arteriosus repair	230
		Valvuloplasty, Truncal valve	240
		Valve replacement, Truncal valve	250
Pulmonary Venous Anomalies	Partial Anomalous Pulmonary Venous Connection	PAPVC repair	260
		PAPVC, Scimitar, Repair	270
	Total Anomalous Pulmonary Venous Connection	TAPVC repair	280
Cor Triatriatum		Cor triatriatum repair	290
Pulmonary Venous Stenosis		Pulmonary venous stenosis repair	300
Systemic Venous Anomalies	Anomalous Systemic Venous Connection	Atrial baffle procedure (non-Mustard, non-Senning)	310
		Anomalous systemic venous connection repair	330
		Systemic venous stenosis repair	340
Right Heart Lesions	Tetralogy of Fallot	TOF repair, No ventriculotomy	350
		TOF repair, Ventriculotomy, Nontransanular patch	360
		TOF repair, Ventriculotomy, Transanular patch	370
		TOF repair, RV-PA conduit	380
		TOF – AVC (AVSD) repair	390
		TOF – Absent pulmonary valve repair	400
	Pulmonary Atresia	Pulmonary atresia – VSD (including TOF, PA) repair	420
		Pulmonary atresia – VSD – MAPCA (pseudotruncus) repair	430
		Unifocalization MAPCA(s)	440
		Occlusion MAPCA(s)	450
	Tricuspid Valve Disease and Ebstein's Anomaly	Valvuloplasty, Tricuspid	460
		Ebstein's repair	465
		Valve replacement, Tricuspid (TVR)	470
		Valve closure, Tricuspid (exclusion, univentricular approach)	480
		Valve excision, Tricuspid (without replacement)	490
		Valve surgery, Other, Tricuspid	500
	RVOT Obstruction, IVS Pulmonary Stenosis	RVOT procedure	510
		1 1/2 ventricular repair	520
		PA, reconstruction (plasty), Main (trunk)	530

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Table 8. *Continued*

Kingdom	Phylum	Procedural Short List Term	STS Harvest Code
		PA, reconstruction (plasty), Branch, Central (within the hilar bifurcation)	540
		PA, reconstruction (plasty), Branch, Peripheral (at or beyond the hilar bifurcation)	550
		DCRV repair	570
	Pulmonary Valve Disease	Conduit reoperation	580
		Valvuloplasty, Pulmonic	590
		Valve replacement, Pulmonic (PVR)	600
		Conduit placement, RV to PA	610
		Conduit placement, LV to PA	620
	Conduit Stenosis/Insufficiency	Valve excision, Pulmonary (without replacement)	630
		Valve closure, Semilunar	640
		Valve surgery, Other, Pulmonic	650
Left Heart Lesions	Aortic Valve Disease	Valvuloplasty, Aortic	660
		Valve replacement, Aortic (AVR)	670
		Valve replacement, Aortic (AVR), Mechanical	680
		Valve replacement, Aortic (AVR), Bioprosthetic	690
		Valve replacement, Aortic (AVR), Homograft	700
		Aortic root replacement, Bioprosthetic	715
		Aortic root replacement, Mechanical	720
		Aortic root replacement, Homograft	730
		Aortic root replacement, Valve sparing	735
		Ross procedure	740
		Konno procedure	750
		Ross-Konno procedure	760
		Other annular enlargement procedure	770
		Aortic stenosis, Subvalvar, Repair	780
		Aortic stenosis, Supravalvar, Repair	790
		Valve surgery, Other, Aortic	800
	Sinus of Valsalva Aneurysm	Sinus of Valsalva, Aneurysm repair	810
	LV to Aorta Tunnel	LV to aorta tunnel repair	820
	Mitral Valve Disease	Valvuloplasty, Mitral	830
		Mitral stenosis, Supravalvar mitral ring repair	840
		Valve replacement, Mitral (MVR)	850
		Valve surgery, Other, Mitral	860
	Hypoplastic Left Heart	Norwood procedure	870
		HLHS biventricular repair	880
	Cardiomyopathy	Transplant, Heart	890
		Transplant, Heart and lung	900
		Partial left ventriculectomy (LV volume reduction surgery) (Batista)	910
	Constrictive Pericarditis	Pericardial drainage procedure	920
		Pericardiectomy	930
		Pericardial procedure, Other	940
Single Ventricle		Fontan, Atrio-pulmonary connection	950
		Fontan, Atrio-ventricular connection	960
		Fontan, TCPC, Lateral tunnel, Fenestrated	970
		Fontan, TCPC, Lateral tunnel, Nonfenestrated	980
		Fontan, TCPC, External conduit, Fenestrated	1000
		Fontan, TCPC, External conduit, Nonfenestrated	1010
		Fontan revision or conversion (Re-do Fontan)	1025
		Fontan, Other	1030
		Ventricular septation	1035
Transposition of the Great Arteries	Congenitally Corrected TGA	Congenitally corrected TGA repair, Atrial switch and ASO (double switch)	1050
		Congenitally corrected TGA repair, Atrial switch and Rastelli	1060
		Congenitally corrected TGA repair, VSD closure	1070
		Congenitally corrected TGA repair, VSD closure and LV to PA conduit	1080
		Congenitally corrected TGA repair, Other	1090

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Table 8. *Continued*

Kingdom	Phylum	Procedural Short List Term	STS Harvest Code
	Transposition of the Great Arteries	Arterial switch operation (ASO)	1110
		Arterial switch operation (ASO) and VSD repair	1120
		Arterial switch procedure + Aortic arch repair	1123
		Arterial switch procedure and VSD repair + Aortic arch repair	1125
		Senning	1130
		Mustard	1140
		Atrial baffle procedure, Mustard or Senning revision	1145
		Rastelli	1150
		REV	1160
		TGA, Other procedures (Nikaidoh, Kawashima, LV-PA conduit, other)	1170
DORV		DORV, Intraventricular tunnel repair	1180
DOLV		DOLV repair	1200
Thoracic Arteries and Veins	Coarctation of Aorta	Coarctation repair, End to end	1210
		Coarctation repair, End to end, Extended	1220
		Coarctation repair, Subclavian flap	1230
		Coarctation repair, Patch aortoplasty	1240
		Coarctation repair, Interposition graft	1250
		Coarctation repair, Other	1260
		Coarctation repair + VSD repair	1275
		Aortic arch repair	1280
		Aortic arch repair + VSD repair	1285
	Coronary Artery Anomalies	Coronary artery fistula ligation	1290
		Anomalous origin of coronary artery from pulmonary artery repair	1291
		Coronary artery bypass	1300
		Coronary artery procedure, Other	1310
	Interrupted Arch	Interrupted aortic arch repair	1320
	Patent Ductus Arteriosus	PDA closure, Surgical	1330
		PDA closure, Device	1340
	Vascular Rings and Slings	Vascular ring repair	1360
		Aortopexy	1365
		Pulmonary artery sling repair	1370
	Aortic Aneurysm	Aortic aneurysm repair	1380
	Aortic Dissection	Aortic dissection repair	1390
Lung Disease	Lung Disease	Lung biopsy	1400
		Transplant, lung(s)	1410
		Lung procedure, Other	1420
	Pectus Excavatum, Carinatum	Pectus repair	1430
	Tracheal Stenosis	Tracheal procedure	1440
Electrophysiologic		Pacemaker implantation, Permanent	1450
		Pacemaker procedure	1460
		ICD (AICD) implantation	1470
		ICD (AICD) ([automatic] implantable cardioverter defibrillator) procedure	1480
		Arrhythmia surgery – atrial, Surgical Ablation	1490
		Arrhythmia surgery – ventricular, Surgical Ablation	1500
Interventional Cardiology Procedures		ASD creation, Balloon septostomy (BAS) (Rashkind)	1520
		ASD creation, Blade septostomy	1530
		Balloon dilation	1540
		Stent placement	1550
		Device closure	1560
		RF ablation	1570
		Coil embolization	1580
Palliative Procedures		Shunt, Systemic to pulmonary, Modified Blalock-Taussig Shunt (MBTS)	1590
		Shunt, Systemic to pulmonary, Central (from aorta or to main pulmonary artery)	1600

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Table 8. *Continued*

Kingdom	Phylum	Procedural Short List Term	STS Harvest Code
		Shunt, Systemic to pulmonary, Other	1610
		Shunt, Ligation and takedown	1630
		PA banding (PAB)	1640
		PA debanding	1650
		Damus-Kaye-Stansel procedure (DKS) (creation of AP anastomosis without arch reconstruction)	1660
		Bidirectional cavopulmonary anastomosis (BDCPA) (bidirectional Glenn)	1670
		Glenn (unidirectional cavopulmonary anastomosis) (unidirectional Glenn)	1680
		Bilateral bidirectional cavopulmonary anastomosis (BBDCPA) (bilateral bidirectional Glenn)	1690
		Hemifontan	1700
		Palliation, Other	1710
Miscellaneous Procedures		Aneurysm, Ventricular, Right, Repair	1720
		Aneurysm, Ventricular, Left, Repair	1730
		Aneurysm, Pulmonary artery, Repair	1740
		Cardiac tumor resection	1760
		Conduit placement, Other	1772
		Conduit placement, Ventricle to aorta	1774
		Pulmonary AV fistula repair/occlusion	1780
		Ligation, Pulmonary artery	1790
		Pulmonary embolectomy, Acute pulmonary embolus	1802
		Pulmonary embolectomy, Chronic pulmonary embolus	1804
		Pleural drainage procedure	1810
		Pleural procedure, Other	1820
		Ligation, Thoracic duct	1830
		Decortication	1840
		Esophageal procedure	1850
		Mediastinal procedure	1860
		Bronchoscopy	1870
		Diaphragm plication	1880
		Diaphragm procedure, Other	1890
		Intraaortic balloon pump (IABP) insertion	1900
		ECMO procedure	1910
		Right/left heart assist device procedure	1920
		VATS (video-assisted thoracoscopic surgery)	1930
		Minimally invasive procedure	1940
		Bypass for noncardiac lesion	1950
		Delayed sternal closure	1960
		Mediastinal exploration	1970
		Sternotomy wound drainage	1980
		Thoracotomy, Other	1990
		Cardiotomy, Other	2000
		Cardiac procedure, Other	2010
		Thoracic and/or mediastinal procedure, Other	2020
		Peripheral vascular procedure, Other	2030
		Miscellaneous procedure, Other	2040
		Organ procurement	2050
		Other procedure	7777

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Table 9. Rules to Define Operative Mortality[21]

1. In The EACTS and The STS Congenital Database, *Operative Mortality* is defined as any death, regardless of cause occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation.
2. If a patient had more than one operation during a hospitalization, assignment of mortality is made to the first operation of the given hospitalization that meets the criteria of an operation type that will be included in the overall programmatic mortality analysis as described in Rule number 10. This operation that would be assigned the mortality can be called the "index operation." (Previously, no useful data was obtained when we allowed the individual surgeon or other data entry personnel to choose the operation to which a given mortality is assigned. We now believe that better data will be obtained by assigning mortality to the first operation of an admission. In the future, algorithmically driven assignment of mortality to the most complex case of the admission might further minimize assignment errors.)
3. The EACTS and STS Congenital Database Reports will employ *patient admission-based operative mortality calculation*. The numerator is the number of patients who have died as measured by the criteria of *Operative Mortality*. The denominator is the number of surgical patient-admissions. Any patient admission that includes one or more cardiac operations of operation types "*CPB*" or "*No CPB Cardiovascular*" will be considered a "cardiovascular surgical admission" and add to the denominator. (Rule number 10 below clarifies which interventions will actually be counted as operations in the EACTS-STS Congenital Database mortality calculations.) It should be noted that the patient who dies after admission but before any surgery will not count as an operative mortality and therefore will not count when calculating patient admission-based operative mortality, unless the patient had prior surgery within 30 days (of the mortality) and is readmitted to the hospital in which case the patient would count as an operative mortality of the prior index operation as described in Rules number 1 and 2 above.
4. Any mortality that occurs for a patient with multiple cardiovascular surgical admissions is assigned to the latest cardiovascular surgical admission. Each cardiovascular surgical admission will be treated as an independent observation. For example, a given patient will contribute only 1 encounter to the total denominator for the single hospitalization for the Norwood (Stage 1) operation even if that particular hospitalization involves multiple operations. If this same patient is discharged home and is later re-admitted and undergoes a superior cavopulmonary connection operation more than 30 days after the Norwood (Stage 1), this patient will now contribute 2 encounters (observations) to the denominator. However, if a patient is readmitted to the hospital and undergoes surgery within 30 days of a prior index operation, mortality is assigned to the earlier index operation.
5. In order for a record to be complete and eligible for mortality analysis, the following database fields must be complete:
   A. Date of Admission
   B. Date of Surgery
   C. Operation Type ("CPB," "No CPB Cardiovascular," "ECMO," "Thoracic," "Interventional Cardiology," or "Other" in the minimum dataset. [CPB is cardiopulmonary bypass and ECMO is extracorporeal membrane oxygenation]. Software vendors may supply other operation types [eg, "CPB Standby," "CPS," "Minor Procedure," "Bronchoscopy," "Other Endoscopy," where CPS is Cardiopulmonary support]; these are converted by the vendor during data harvest export to the appropriate operation type from the official list of choices. For example, operations coded as "Minor Procedure" are converted by the vendor during data harvest export to Operation Type "Other.")
   D. Primary Diagnosis
   E. Primary Procedure
   F. Discharge Status (Alive or Dead)
   G. 30-day Status (Alive or Dead).

   A record cannot be included in the mortality analysis until both Discharge Status and 30-day Status fields are completed.
6. Patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will not be included in the mortality calculation in the EACTS and The STS Congenital Database reports. (We acknowledge that mortality after surgical PDA closure in low-birth weight premature infants can be related to surgical judgment or technique; however, the vast majority of deaths in this patient population are multifactorial and largely unrelated to the surgical procedure in time and by cause. Therefore, because mortality in this patient group could potentially impact significantly on the expression of overall programmatic mortality, we have decided to exclude from mortality analysis patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure.)
7. If a patient was admitted from their home, they must be either dead or discharged to home prior to completing the field discharge status. If a patient was admitted from their home, the field discharge status can not be completed if the patient is transferred to another acute care facility or chronic care facility until they are either dead or discharged to home. However, if this patient survives in a chronic care facility for 6 postoperative months (ie, 183 postoperative days), the patient can then be considered "alive" in the discharge status field. (Some institutions may not have a setup that allows transfer to a chronic care facility and instead utilizes their own institution as the chronic care facility. If an institution does not utilize a chronic care facility and instead keeps these chronic patients in-house, this institution can apply to this Rule [number 7] whenever one of their patients survives for 6 postoperative months (ie, 183 postoperative days) on "chronic care status" within their institution.)
8. If a patient was admitted from (ie, transferred from) a chronic care facility where they chronically reside, they must be either dead or discharged either to home or to a chronic care facility prior to completing the field discharge status.
9. If a patient was admitted from (ie, transferred from) another acute care facility, Rule number 7 as previously stated applies if they lived at home prior to their admission to the transferring acute care facility. If a patient was transferred from another acute care facility, Rule number 8 as previously stated applies if they lived in a chronic care facility prior to their admission to the transferring acute care facility.
10. Only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included in the overall programmatic mortality analysis. (All cases classified as operation "*CPB*" and "*No CPB Cardiovascular*" will be included in the mortality analysis except for patients weighing less than or equal to 2,500 g undergoing PDA (patent ductus arteriosus) ligation as their primary procedure, as discussed in Rule number 6 above, and organ procurement cases, as discussed in Rule number 11 below).

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Table 9. *Continued*

11. Operations coded as operation type "*CPB Standby*" will be converted to operation type "*No CPB Cardiovascular*" by the software vendor prior to analysis, with two exceptions: (1) Pectus repair procedure coded as "*CPB Standby*" should be converted to operation type "*Thoracic*" and (2) purely bronchoscopic procedures coded as "*CPB Standby*" should be converted by the vendor to operation type "*Bronchoscopy*" if it is an available option, or by the vendor to operation type "*Thoracic*." (Centers and surgeons may use cardiopulmonary bypass standby or ECMO standby when performing the Nuss pectus repair or complex bronchoscopic interventions. While other "*CPB Standby*" operations are converted appropriately to operation type "*No CPB Cardiovascular*" by the software vendor prior to analysis, these two examples are best not analyzed as "*No CPB Cardiovascular*" cases in the mortality analysis.) Lung transplantation employing CPB will be coded as such, whilst lung transplantation without CPB will be coded as "*No CPB Cardiovascular.*" Organ procurement is coded as operation type "*No CPB Cardiovascular*," but will be excluded from both the numerator and the denominator in all mortality analysis.
12. Operation types "*ECMO*," "*Thoracic*," "*Interventional Cardiology*," and "*Other*" will not be included in the overall programmatic mortality analysis. Minor procedures, such as central line placement procedures or arterial line placement procedures and similar vascular access procedures, will count as operation type "*Other*" and will not be included in the overall programmatic mortality analysis.
13. When measuring both programmatic volume and programmatic mortality, only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included. When measuring both programmatic volume and programmatic mortality, Operation types "*ECMO,*" and "*Thoracic*," "*Interventional Cardiology*" and "*Other*" will not be included. Therefore, minor procedures such as central line placement procedures will not be included in programmatic volume or mortality measurements. Although organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the mortality analysis, they will be included in programmatic volume measurement. Thus, only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included in the mortality analysis; and as stated above, organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the numerator and the denominator of the mortality analysis.

Reference:

Jacobs JP, Mavroudis C Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. *What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee*. Ann Thorac Surg 2006; 81: 1937–1941.

Table 10. Rules to Define Operative Morbidity[22]

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 *intraoperative complication* is any complication that occurs or is recognized during the time interval between the database field, OR Entry Date and Time, and the database field, OR Exit Date and Time.

A *postoperative complication* is any complication that occurs or is recognized during the time interval between OR Exit Date and Time and the end of the period of data collection.

An *operative complication* is any complication that occurs during the time interval between OR Entry Date and Time and the end of the period of data collection, and thus includes both intraoperative and postoperative complications.

A *preoperative complication* is any complication that occurs or is recognized before the database field, OR Entry Date and Time.

Time intervals used in the EACTS and STS Congenital Heart Databases

1. **OR Entry Date and Time**: OR entry date and time is defined as the time, to the nearest minute (using 24-hour clock), that the patient entered the operating room. If the procedure was performed in a location other than the OR, record the time when the sterile field, or its equivalent, was set up.
2. **OR Exit Date and Time**: OR exit time date and time is defined as the time, to the nearest minute (using 24-hour clock), that the patient exits the operating room. If the procedure was performed in a location other than the OR, record the time when the sterile field, or its equivalent, was taken down.
3. **Operating Room Time (OR Time)**: OR time is the time interval between the time when the operation begins and the time when the operation ends. This calculated time interval begins at OR Entry Time and ends at OR Exit Time (Definition 2 minus Definition 1).
4. **Skin Incision Date and Time**: Skin incision date and time is defined as the time, to the nearest minute (using 24-hour clock), that the skin incision, or its equivalent, was made. For example, during bronchoscopy, one would utilize the bronchoscope insertion time.
5. **Skin Closure Date and Time**: Skin incision date and time is defined as the time, to the nearest minute (using 24-hour clock), that the skin incision was closed, or its equivalent (i.e. removal of bronchoscope). If the patient leaves the operating room with an open incision, collect the time that the dressings were applied to the incision.
6. **Procedure Time**: Procedure time is the time interval between the time when the procedure begins and the time when the procedure ends. This calculated time interval begins at Skin Incision Start Time and ends at Skin Closure Time (Definition 5 minus Definition 4).
7. **Hospital Admission Date**: The hospital admission date is the date the patient was admitted to the hospital. For those patients who originally enter the hospital in an outpatient capacity (i.e. for preoperative catheterization), but then are not discharged, the admit date is the date of the patient's entry into the hospital.

Table 10. *Continued*

8. **EACTS-STS Congenital Database Discharge Date**: In the EACTS and STS Congenital Heart Surgery Databases, the date and time of discharge is determined by three rules (presented below), which specify how to complete the field "EACTS-STS Congenital Database Discharge Date" and are consistent with previously published rules defining Operative Mortality and how to complete the field "Discharge Status (Alive or Dead)" [2].
9. **EACTS-STS Length of stay**: The EACTS-STS Congenital Database length of stay for a hospitalization is the time interval between the hospital admission and the EACTS-STS Congenital Database Discharge Date (Definition 8 minus Definition 7).
10. **EACTS-STS Postoperative Length of Stay**: The postoperative length of stay for a hospitalization is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the time of EACTS-STS Database discharge (Definition 8 minus Definition 2).
11. **Hospital Discharge Date**: In rare instances, the Hospital Discharge Date differs from the EACTS-STS Congenital Database Discharge Date. The Hospital Discharge Date is the date and time that the patient is discharged from the hospital where the surgery took place. In situations where the patient is discharged to another acute care facility or to a chronic care facility, the Hospital Discharge Date is the date the patient is transferred from the hospital where the surgery took place to another facility.
12. **Hospital Length of Stay**: The hospital length of stay is the time interval between the hospital admission and the hospital discharge (Definition 11 minus Definition 7).
13. **Hospital Postoperative Length of Stay**:The hospital postoperative length of stay is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the hospital discharge (Definition 11 minus Definition 2).
14. **Intubation Date and Time**: The Intubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support started. The following guidelines are offered in the STS Database Specifications version 2.50:
    1. Capture the intubation closest to the surgical start time. If the patient was intubated upon admission and remained intubated until the surgical start time, capture this intubations date and time.
    2. If the patient was admitted intubated (intubated at another institution) and remained continually intubated until the surgical start time, capture the patient's admission date and time.
    3. If the patient was admitted with a tracheostomy in place without ventilatory support, capture the date and time closest to the surgical start time that ventilatory support was initiated.
    4. If the patient was admitted with a tracheostomy in place receiving chronic ventilatory support, capture the admission date and time.
    5. If the intubation date and time is otherwise unknown, enter the date and time the patient entered the operating room.
    6. Do not alter the previously established date and time that ventilatory support was initiated for scenarios including, but not limited to, interruptions in ventilatory support due to accidental extubation/de-cannulation, elective tube change etc.
15. **Initial Extubation Date and Time**: The Initial Extubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support initially ceased after surgery. The following guidelines are offered in the STS Database Specifications version 2.50:
    1. Capture the extubation closest to the surgical stop time.
    2. If the patient has a tracheostomy and is separated from the mechanical ventilator postoperatively within the hospital admission, capture the date and time of separation from the mechanical ventilator closest to the surgical stop time.
    3. If the patient expires while intubated or cannulated and on the ventilator, capture the date and time of expiration.
    4. If patient discharged on chronic ventilatory support, capture the date and time of discharge.
16. **Final Extubation Date and Time**: The Final Extubation Date and Time is defined as the date (mm/dd/yyyy) and time (hh:mm) (24 hour clock) ventilatory support last ceased prior to discharge after surgery. The following guidelines are offered in the STS Database Specifications version 2.50:
    1. Capture the extubation time closest to EACTS-STS Congenital Database Discharge Date.
    2. If the patient has a tracheostomy and is separated from the mechanical ventilator more than once postoperatively within the hospital admission, capture the date and time of separation from the mechanical ventilator closest to the EACTS-STS Congenital Database Discharge Date.
    3. If the patient expires while intubated or cannulated and on the ventilator, capture the date and time of expiration.
    4. If the patient was discharged on chronic ventilatory support, capture the date and time of the EACTS-STS Congenital Database Discharge.
17. **Postoperative length of time until initial extubation**: The postoperative length of time until initial extubation is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Initial Extubation Date and Time (Definition 15 minus Definition 2).
18. **Postoperative length of time until final extubation**: The postoperative length of time until final extubation is the time interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Final Extubation Date and Time (Definition 16 minus Definition 2).
19. **Postoperative Length of ICU Stay**: The postoperative length of ICU stay is the time interval between admission to the ICU following surgery and final discharge from the ICU.

Rules to determine the EACTS-STS Congenital Heart Database Discharge Date

These following three rules are used to determine the EACTS-STS Congenital Database Discharge Date. These rules are consistent with the current STS Database Specifications version 2.50 definition of "Discharge Date": "*Indicate the date on which the patient was discharged from the hospital. This is intended to capture the total length of stay in your hospital regardless of the medical service managing the patient*"

A. If a patient was admitted from their home, they must be either dead or discharged to home prior to completing the field "EACTS-STS Discharge Date". Their "EACTS-STS Discharge Date" is the date they are discharged to home or their date of mortality. If a patient was

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Table 10. *Continued*

admitted from their home, the field "EACTS-STS Discharge Date" can not be completed if the patient is transferred to another acute care facility or chronic care facility until they are either dead or discharged to home. However, if this patient survives in a chronic care facility for 6 postoperative months (i.e., 183 postoperative days), the patient can then be assigned an "EACTS-STS Discharge Date" that is the date when the patient is in the chronic care facility for 183 days. (Some institutions may not have a mechanism that allows transfer to a chronic care facility and instead utilizes their own institution as the chronic care facility. If an institution does not utilize a chronic care facility and instead keeps these chronic patients in-house, this institution can apply to this Rule [Rule A] whenever one of their patients survives for 6 postoperative months (i.e., 183 postoperative days) on "chronic care status" within their institution.)

B. If a patient was admitted from (i.e., transferred from) a chronic care facility where they chronically reside, they must be either dead or discharged either to home or to a chronic care facility prior to completing the field "EACTS-STS Discharge Date". Their "EACTS-STS Discharge Date" is the date they are discharged either to home or to a chronic care facility, or their date of mortality.

C. If a patient was admitted from (i.e., transferred from) another acute care facility, Rule A as previously stated applies if they lived at home prior to their admission to the transferring acute care facility. If a patient was transferred from another acute care facility, Rule B as previously stated applies if they lived in a chronic care facility prior to their admission to the transferring acute care facility.

Reference:

Jacobs JP, Jacobs ML, Mavroudis C, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ, Vener DF, Barach P, Benavidez OJ, Bacha EA. *What is Operative Morbidity? Defining Complications in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee*. Ann Thorac Surg 2007; 84: 1416–1421.

Table 11. Short List of Complications prepared for The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
General definitions	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.
General definitions	Complication-modifier for complication type, Adverse event	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.
No complications	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 breech in the standard of care that constitutes medical negligence or medical malpractice.

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
No complications	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 breech in the standard of care that constitutes medical negligence or medical malpractice.
Death	Intraoperative death or intraprocedural death	Patient died in the operating room or procedure room (such as catheterization laboratory or hybrid suite).
Death	Operative mortality	Operative Mortality is defined as any death, regardless of cause occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation.
Readmission	Unplanned readmission to the hospital within 30 days of surgery or intervention	Any unplanned readmission to the hospital within 30 days of surgery or intervention
Multiple	Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)	Multi-System Organ Failure (MSOF) is a condition where more than one organ system has failed (for example, respiratory failure requiring mechanical ventilation combined with renal failure requiring dialysis). Please code the individual organ system failures as well. If MSOF is associated with sepsis as well, please also code: "Sepsis, Multi-system Organ Failure". Multi-System Organ Failure (MSOF) is synonymous with Multi-Organ Dysfunction Syndrome (MODS).
Cardiac	Cardiac arrest, Timing = Cardiac arrest (MI) during or following procedure (Perioperative/ Periprocedural = Intraoperative/ Intraprocedural and/or Postoperative/ Postprocedural)	A cardiac arrest is the cessation of effective cardiac mechanical function. This complication should be selected if the cardiac arrest developed after OR Entry Date and Time.
Cardiac	Cardiac dysfunction resulting in low cardiac output	Low cardiac output state characterized by some of the following: tachycardia, oliguria, decreased skin perfusion, need for increased inotropic support (10% above baseline at admission), metabolic acidosis, widened Arterial—Venous oxygen saturation, need to open the chest, or need for mechanical support. If the cardiac dysfunction is of a severity that results in inotrope dependence, mechanical circulatory support, or listing for cardiac transplantation, please also code as "Cardiac failure (severe cardiac dysfunction)".
Cardiac	Cardiac failure (severe cardiac dysfunction)	Low cardiac output state characterized by some of the following: tachycardia, oliguria, decreased skin perfusion, need for increased inotropic support (10% above baseline at admission), metabolic acidosis, widened Arterial—Venous oxygen saturation, need to open the chest, or need for mechanical support. This complication should be selected if the cardiac dysfunction is of a severity that results in inotrope dependence, mechanical circulatory support, or listing for cardiac transplantation.
Cardiac	Endocarditis-postprocedural infective endocarditis	Infective endocarditis in the setting of a heart which has been altered by surgery or intervention. Duke Criteria for the Diagnosis of Infective Endocarditis (IE): The definitive diagnosis of infective endocarditis requires one of the following four situations: 1) Histologic and/or microbiologic evidence of infection at surgery or autopsy such as positive valve culture or histology; 2) Two major criteria; 3) One major criterion and three minor criteria; 4) Five minor criteria. The two major criteria are: 1) Blood cultures positive for IE 2) Evidence of endocardial involvement. Blood cultures positive for IE requires: 1) Typical microorganism consistent with IE isolated from 2 separate blood cultures, as noted in number two below (viridans streptococci, Streptococcus bovis, Staphylococcus

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
		aureus, or HACEK group [HACEK, Haemophilus species {H. aprophilus and H. paraaphrophilus}, Actinobacillus actinoinycetemcomitans, Cardiobacterium hominis, Eikenella corrodens, and Kingella kingae.]) or (Community-acquired enterococci in the absence of a primary focus); 2) Microorganisms consistent with IE isolated from persistently positive blood cultures defined as: (At least 2 positive cultures of blood samples obtained > 12 hours apart) or (All of 3 or a majority of 4 or more separate cultures of blood, the first and the last sample obtained > 1 hr apart); 3) Single blood culture positive for Coxiella burnetii or an antiphase I IgG antibody titer of >1 :800. Evidence of endocardial involvement requires 1) Positive results of echocardiography for IE defined as: (Oscillating intracardiac mass on the valve or supporting structures in the path of regurgitant jets or on implanted material in the absence of an alternative anatomic explanation) or (Abscess) or (New partial dehiscence of a valvular prosthesis) or 2) New valvular regurgitation (worsening or changing or preexisting murmur not sufficient). The six minor criteria are: 1) Predisposing heart disease or injection drug use (IVDA); 2) Temperature of > 38C; 3) Vascular phenomenon (major arterial emboli, septic pulmonary infarcts, mycotic aneurysm, intracranial or conjunctival hemorrhage, Janeway's lesions); 4) Immunologic phenomenon (glomerulonephritis, Osler's nodes, Roth's spots, rheumatoid factor); 5) Microbiologic evidence (a positive blood culture that does not meet a major criterion as noted above) or serologic evidence of active infection with an organism consistent with IE; 6) Echocardiographic findings that are consistent with IE but do not meet a major criterion as noted above. References: 1) Dhawan VK Infectious Endocarditis in Elderly Patients. Clin. Infect. Dis. 2002;34:806-812. 2) Durack DT, Lukes AS, Bright DK. New criteria for diagnosis of infective endocarditis: utilization of specific echocardiographic findings. Duke Endocarditis Service. Am. J. Med. 1994;96:200-209. 3) Li IS, Sexton DJ, Mick N, et al. Proposed modifications to the Duke criteria for the diagnosis of infective endocarditis. Clin. Infect. Dis. 2000;30:633-638. 4) http://gold.aecom.yu.edu/id/almanac/dukeendocarditis.htm, accessed July 5, 2006.
Cardiac	Pericardial effusion, Requiring drainage	Abnormal accumulation of fluid in the pericardial space, Requiring drainage, By any technique.
Cardiac	Pulmonary hypertension	Clinically significant elevation of pulmonary arterial pressure, requiring intervention. Typically the mean pulmonary arterial pressure is greater than 25 mmHg in the presence of a normal pulmonary arterial occlusion pressure (wedge pressure).
Cardiac	Pulmonary hypertensive crisis (PA pressure > systemic pressure)	An acute state of inadequate systemic perfusion associated with pulmonary hypertension, when the pulmonary arterial pressure is greater than the systemic arterial pressure.
Cardiac	Pulmonary vein obstruction	Clinically significant stenosis or obstruction of pulmonary veins. Typically diagnosed by echocardiography or cardiac catheterization, this may present with or without symptoms.
Cardiac	Systemic vein obstruction	Clinically significant stenosis or obstruction of any major systemic vein (e.g., superior vena cava, inferior vena cava, femoral veins, internal jugular veins, etc.).
Operative/ Procedural	Bleeding, Requiring reoperation	Postoperative/postprocedural bleeding requiring reoperation
Operative/ Procedural	Sternum left open, Planned	Sternum was left open postoperatively with preoperative plans to leave the sternum open postoperatively (i.e. planned). The goal is for delayed sternotomy closure.
Operative/ Procedural	Sternum left open, Unplanned	Sternum was left open postoperatively without preoperative plans to leave the sternum open postoperatively (i.e. unplanned). The goal is for delayed sternotomy closure.

Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
Operative/ Procedural	Unplanned cardiac reoperation during the postoperative or postprocedural time period	Any additional unplanned cardiac operation 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. A cardiac operation is defined as any operation that is of the operation type of "CPB" or "No CPB Cardiovascular".
Operative/ Procedural	Unplanned interventional cardiovascular catheterization procedure during the postoperative or postprocedural time period	Any unplanned interventional cardiovascular catheterization procedure 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/ Procedural	Unplanned reoperation during the postoperative or postprocedural time period	Any additional unplanned operation 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.
Mechanical support utilization	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.
Arrhythmia	Arrhythmia	"Arrhythmia" ROOT Definition = Any cardiac rhythm other than Normal Sinus Rhythm (non-NSR). If pacemaker is required, also code "Arrhythmia necessitating pacemaker". (Although some arrhythmias will require treatment and some arrhythmias will not require treatment, this list will define all arrhythmias. Many databases will choose to track as complications only those arrhythmias that require treatment.) The definition of arrhythmia from The World Health Organization and The International Society of Cardiology Task Force is as follows: An arrhythmia is defined as "any cardiac rhythm other than the normal sinus rhythm. Such a rhythm may be either of sinus or ectopic origin, and either regular or irregular. An arrhythmia may be due to a disturbance in impulse formation or conduction, or both".
Arrhythmia	Arrhythmia requiring drug therapy	Arrhythmia (ROOT Definition) + An arrhythmia requiring drug therapy
Arrhythmia	Arrhythmia requiring electrical cardioversion or defibrillation	Arrhythmia (ROOT Definition) + An arrhythmia requiring electrical cardioversion or defibrillation
Arrhythmia—Arrhythmia necessitating pacemaker	Arrhythmia necessitating pacemaker, Permanent pacemaker	Implantation and utilization of a permanent pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block).
Arrhythmia—Arrhythmia necessitating pacemaker	Arrhythmia necessitating pacemaker, Temporary pacemaker	Implantation and utilization of a temporary pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block).
Pulmonary	Chylothorax	Presence of lymphatic fluid in the pleural space, commonly secondary to leakage from the thoracic duct or one of its main tributaries. Thoracocentesis is the gold standard for diagnosis and generally reveals a predominance of lymphocytes and/or a triglyceride level greater than 110 mg/dL
Pulmonary	Pleural effusion, Requiring drainage	Abnormal accumulation of fluid in the pleural space, Requiring drainage, By any technique.
Pulmonary	Pneumonia	"Pneumonia" ROOT Definition = Pneumonia is defined as a "respiratory disease characterized by inflammation of the lung parenchyma (including alveolar spaces and interstitial tissue), most commonly caused by infection". Pneumonia is diagnosed by appropriate clinical findings (such as fever, leukopenia or leukocytosis, and new onset of purulent sputum) and one or more of the following: positive cultures (of sputum or pulmonary secretions)

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
		and/or pulmonary infiltrate on chest X-ray. An endotracheal tube culture may or may not be positive. Patients commonly demonstrate an evolving area of focal lung consolidation accompanied by fever (>38.5). Pneumonia (pneumonitis) may affect an entire lobe (lobar pneumonia), a segment of a lobe (segmental or lobular pneumonia), alveoli contiguous to bronchi (bronchopneumonia), or interstitial tissue (interstitial pneumonia). These distinctions are generally based on X-ray observations.
Pulmonary	Pneumothorax	A collection of gas in the pleural space resulting in collapse of the lung on the affected side.
Pulmonary	Postoperative/Postprocedural respiratory insufficiency requiring mechanical ventilatory support >7 days	Respiratory Insufficiency requiring mechanical ventilatory support from surgery or procedure to greater than 7 days postoperatively/ postprocedurally. In other words, the inability of the patient to exchange oxygen and carbon dioxide in sufficient quantities to avoid unacceptable hypercarbia, hypoxemia, or both, without mechanical support for greater than 7 days during the postoperative or postprocedural period.
Pulmonary	Postoperative/Postprocedural respiratory insufficiency requiring reintubation	Reintubation required after initial extubation. In other words, the need to reinstitute postoperative or postprocedural mechanical ventilation after a planned extubation and prior to discharge, or after a planned extubation and after discharge but within 30 days of surgery.
Pulmonary	Respiratory failure, Requiring tracheostomy	Failure to wean from mechanical ventilation necessitating the creation of a surgical airway
Renal	Renal failure – acute renal failure, Acute renal failure requiring dialysis at the time of hospital discharge	Renal failure – acute renal failure (ROOT Definition) + With new postoperative/postprocedural requirement for dialysis, including peritoneal dialysis and/or hemodialysis. Code this complication if the patient requires dialysis at the time of hospital discharge or death in the hospital. (This complication should be chosen only if the dialysis was associated with acute renal failure.) {"Renal failure – acute renal failure" ROOT Definition = Acute renal failure is defined as new onset oliguria with sustained urine output<0.5 cc/kg/hr for 24 hours and/or a rise in creatinine > 1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal dialysis and/or hemodialysis) or hemofiltration. Acute renal failure that will be counted as an operative or procedural complication must occur prior to hospital discharge or after hospital discharge but within 30 days of the procedure. (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.) The complication is to be coded even if the patient required dialysis, but the treatment was not instituted due to patient or family refusal.}
Renal	Renal failure – acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge	Renal failure – acute renal failure (ROOT Definition) + With new postoperative/postprocedural requirement for temporary dialysis, including peritoneal dialysis and/or hemodialysis. Code this complication if the patient does not require dialysis at the time of hospital discharge or death in the hospital. (This complication should be chosen only if the dialysis was associated with acute renal failure.) {"Renal failure – acute renal failure" ROOT Definition = Acute renal failure is defined as new onset oliguria with sustained urine output <0.5 cc/kg/hr for 24 hours and/or a rise in creatinine >1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
		dialysis and/or hemodialysis) or hemofiltration. Acute renal failure that will be counted as an operative or procedural complication must occur prior to hospital discharge or after hospital discharge but within 30 days of the procedure. (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.) The complication is to be coded even if the patient required dialysis, but the treatment was not instituted due to patient or family refusal.}
Renal	Renal failure – acute renal failure, Acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge	Renal failure – acute renal failure (ROOT Definition) + With new postoperative/postprocedural requirement for temporary hemofiltration. Code this complication if the patient does not require dialysis at the time of hospital discharge or death in the hospital. (This complication should be chosen only if the hemofiltration was associated with acute renal failure.) {"Renal failure – acute renal failure" ROOT Definition = Acute renal failure is defined as new onset oliguria with sustained urine output$<$0.5 cc/kg/hr for 24 hours and/or a rise in creatinine $>$ 1.5 times upper limits of normal for age (or twice the most recent preoperative/preprocedural values if these are available), with eventual need for dialysis (including peritoneal dialysis and/or hemodialysis) or hemofiltration. Acute renal failure that will be counted as an operative or procedural complication must occur prior to hospital discharge or after hospital discharge but within 30 days of the procedure. (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.) The complication is to be coded even if the patient required dialysis, but the treatment was not instituted due to patient or family refusal.}
Infectious	Sepsis	"Sepsis" ROOT Definition = Sepsis is defined as "evidence of serious infection accompanied by a deleterious systemic response". In the time period of the first 48 postoperative or postprocedural hours, the diagnosis of sepsis requires the presence of a Systemic Inflammatory Response Syndrome (SIRS) resulting from a proven infection (such as bacteremia, fungemia or urinary tract infection). In the time period after the first 48 postoperative or postprocedural hours, sepsis may be diagnosed by the presence of a SIRS resulting from suspected or proven infection. During the first 48 hours, a SIRS may result from the stress associated with surgery and/or cardiopulmonary bypass. Thus, the clinical criteria for sepsis during this time period should be more stringent. A systemic inflammatory response syndrome (SIRS) is present when at least two of the following criteria are present: hypo- or hyperthermia ($>$38.5 or $<$36.0), tachycardia or bradycardia, tachypnea, leukocytosis or leukopenia, and thrombocytopenia.
Neurologic	Neurological deficit, Neurological deficit persisting at discharge	Newly recognized and/or newly acquired deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similarly unaffected inpatient, With a persisting neurologic deficit present at hospital discharge. In other words, new (onset intraoperatively or postoperatively – or intraprocedurally or postprocedurally) neurological deficit persisting and present at discharge from hospital.

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
Neurologic	Neurological deficit, Transient neurological deficit not present at discharge	Newly recognized and/or newly acquired deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similarly unaffected inpatient, With no persisting neurologic deficit present at hospital discharge. In other words, new (onset intraoperatively or postoperatively – or intraprocedurally or postprocedurally) neurological deficit completely resolving prior to discharge from hospital.
Neurologic	Paralyzed diaphragm (possible phrenic nerve injury)	Presence of elevated hemi-diaphragm(s) on chest radiograph in conjunction with evidence of weak, immobile, or paradoxical movement assessed by ultrasound or fluoroscopy.
Neurologic	Peripheral nerve injury, Neurological deficit persisting at discharge	Peripheral nerve injury (ROOT Definition) + With a persisting neurologic deficit present at hospital discharge. {"Peripheral nerve injury" ROOT Definition = Newly acquired or newly recognized deficit of unilateral or bilateral peripheral nerve function indicated by physical exam findings, imaging studies, or both.}
Neurologic	Seizure	"Seizure" ROOT Definition = A seizure is defined as the clinical and/or electroencephalographic recognition of epileptiform activity.
Neurologic	Spinal cord injury, Neurological deficit persisting at discharge	Spinal cord injury (ROOT Definition) + With a persisting neurologic deficit present at hospital discharge. {"Spinal cord injury" ROOT Definition = Newly acquired or newly recognized deficit of spinal cord function indicated by physical exam findings, imaging studies, or both.}
Neurologic	Stroke	"Stroke" ROOT Definition = A stroke is any confirmed neurological deficit of abrupt onset caused by a disturbance in blood flow to the brain, when the neurologic deficit does not resolve within 24 hours.
Neurologic	Vocal cord dysfunction (possible recurrent laryngeal nerve injury)	Presence of poor or no vocal cord movement assessed by endoscopy. Patient may or may not have stridor, hoarse voice or poor cry, in conjunction with endoscopic findings.
Wound	Wound dehiscence (sterile)	"Wound dehiscence (sterile)" ROOT Definition = "Wound dehiscence (sterile)" is defined as separation of the layers of a surgical wound. This separation can either be superficial or deep and can include the sternum in the case of a median sternotomy incision. When the sterile separation includes the skin and sternum, in the case of a median sternotomy incision, use this code ("Wound dehiscence (sterile)"). The code "Sternal instability (sterile)" should be used to record the complication when the superficial and deep layers of the incision remain intact but non-union of the sternal edges is present. Causes of wound dehiscence can include tissue ischemia, nutritional deficiencies, use of corticosteroids, vitamin C deficiency, and others. Wound dehiscence due to wound infection should be recorded as a wound infection.
Wound	Wound dehiscence (sterile), Median sternotomy	Wound dehiscence (sterile) (ROOT Definition) + Location = Median sternotomy
Wound	Wound infection	"Wound infection" ROOT Definition = Erythema, possible induration and possible fluctuance of a surgical wound (surgical site) with possible drainage and possible tissue separation. Though wound cultures may be positive, this is not an absolute requirement for establishing this clinical diagnosis.
Wound	Wound infection-Deep wound infection	"Wound infection-Deep wound infection" ROOT Definition = A deep wound infection involves the deep soft tissues (e.g., fascial and muscle layers) of the incision AND the patient has at least ONE of the following numbered features: 1) Purulent drainage from the deep portion of the incision (but not from the organ/space component of the surgical site and no evidence of sternal osteomyelitis), 2) The deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has ONE of the following lettered signs or symptoms (unless the incision is culture negative): A) fever, B) localized pain, or C) tenderness, 3) An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or

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Table 11. *Continued*

Organ System	Short List of Intraoperative and Postoperative Complications Version 2009	Updated Definitions
		radiologic examination, or 4) A diagnosis of a deep wound infection by a surgeon or by an attending physician.
Wound	Wound infection-Mediastinitis	The diagnosis of mediastinitis must meet one of the following criteria: Criterion 1: Patient has organisms cultured from mediastinal tissue or fluid that is obtained during a surgical operation or by needle aspiration. Criterion 2: Patient has evidence of mediastinitis by histopathologic examination or visual evidence of mediastinitis seen during a surgical operation. Criterion 3: Patient has at least ONE of the following numbered signs or symptoms with no other recognized cause: 1) fever, 2) chest pain, or 3) sternal instability AND at least one of the following numbered features: 1) purulent mediastinal drainage, 2) organisms cultured from mediastinal blood, drainage or tissue, or 3) widening of the cardio-mediastinal silhouette. Criterion 4: Patient ⩽ 1 year of age has at least one of the following numbered signs or symptoms with no other recognized cause: 1) fever, 2) hypothermia, 3) apnea, 4) bradycardia, or 5) sternal instability AND at least one of the following numbered features: 1) purulent mediastinal discharge, 2) organisms cultured from mediastinal blood, drainage or tissue, or 3) widening of the cardio-mediastinal silhouette. Infections of the sternum (sternal osteomyelitis) should be classified as mediastinitis. Sternal instability that is not associated with a wound infection or mediastinitis is documented as "Sternal instability".
Wound	Wound infection-Superficial wound infection	"Wound infection-Superficial wound infection" ROOT Definition = A superficial wound infection must meet the following numbered criteria: 1) The infection involves only the skin and the subcutaneous tissue of the incision and 2) The patient has at least ONE of the following lettered features: A) purulent drainage from the superficial portion of the incision, B) organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial portion of the incision, C) at least ONE of the following numbered signs or symptoms: [1] pain or tenderness, [2] localized swelling, redness, or heat, and [3] the superficial portion of the incision is deliberately opened by a surgeon, unless the incision is culture negative, or D) a diagnosis of superficial wound infection by the surgeon or by the attending physician.
Other	Other complication	Any complication not otherwise specified in this list. 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.
Other	Other operative/procedural complication	Any complication not otherwise specified in this list that occurs prior to discharge, or after discharge but within 30 days of surgery or intervention. (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.)

This Table (Table 11) provides the latest version of the Short List of Complications prepared for The Congenital Heart Surgery Databases of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons. This version is a draft work in progress that was developed by updating the current version 2.50 Short List of Complications of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, so that the new Short List of Complications shown in Table 11 is consistent and harmonized with *The Long List of Complications of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease* published in Part IV of this Supplement.

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