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Original Article

Nomenclature and databases for the surgical treatment of congenital cardiac disease – an updated primer and an analysis of opportunities for improvement

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Abstract This review discusses the historical aspects, current state of the art, and potential future advances in the areas of nomenclature and databases for the analysis of outcomes of treatments for patients with congenitally malformed hearts. We will consider the current state of analysis of outcomes, lay out some principles which might make it possible to achieve life-long monitoring and follow-up using our databases, and describe the next steps those involved in the care of these patients need to take in order to achieve these objectives. In order to perform meaningful multi-institutional analyses, we suggest that any database must incorporate the following six essential elements: use of a common language and nomenclature, use of an established uniform core dataset for collection of information, incorporation of a mechanism of evaluating case complexity, availability of a mechanism to assure and verify the completeness and accuracy of the data collected, collaboration between medical and surgical subspecialties, and standardised protocols for life-long follow-up.

During the 1990s, both The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons created databases to assess the outcomes of congenital cardiac surgery. Beginning in 1998, these two organizations collaborated to create the International Congenital Heart Surgery Nomenclature and Database Project. By 2000, a common nomenclature, along with a common core minimal dataset, were adopted by The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, and published in the Annals of Thoracic Surgery. In 2000, The International Nomenclature Committee for Pediatric and Congenital Heart Disease was established. This committee eventually evolved into the International Society for Nomenclature of Paediatric and Congenital Heart Disease. The working component of this international nomenclature society has been The International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Nomenclature Working Group. By 2005, the Nomenclature Working Group crossmapped 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 with the European Paediatric Cardiac Code of the Association for European Paediatric Cardiology, and therefore created the International Paediatric and Congenital Cardiac Code, which is available for free download from the internet at [http://www.IPCCC.NET].

This common nomenclature, the International Paediatric and Congenital Cardiac Code, and the common minimum database data set created by the International Congenital Heart Surgery Nomenclature and Database Project, are now utilized by both The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons. Between 1998 and 2007 inclusive, this nomenclature and database was used by both of these two organizations to analyze outcomes of over 150,000 operations involving patients undergoing surgical treatment for congenital cardiac disease.

Two major multi-institutional efforts that have attempted to measure the complexity of congenital heart surgery are the Risk Adjustment in Congenital Heart Surgery-1 system, and the Aristotle Complexity Score. Current efforts to unify the Risk Adjustment in Congenital Heart Surgery-1 system and the Aristotle Complexity Score are in their early stages, but encouraging. Collaborative efforts involving The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons are under way to develop mechanisms to verify the completeness and accuracy of the data in the databases. Under the leadership of The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, further collaborative efforts are ongoing between congenital and paediatric cardiac surgeons and other subspecialties, including paediatric cardiac anaesthesiologists, via The Congenital Cardiac Anesthesia Society, paediatric cardiac intensivists, via The Pediatric Cardiac Intensive Care Society, and paediatric cardiologists, via the Joint Council on Congenital Heart Disease and The Association for European Paediatric Cardiology.

In finalising our review, we emphasise that analysis of outcomes must move beyond mortality, and encompass longer term follow-up, including cardiac and non cardiac morbidities, and importantly, those morbidities impacting health related quality of life. Methodologies must be implemented in these databases to allow uniform, protocol driven, and meaningful, long term follow-up.

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

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 surgeons, cardiologists, anaesthesiologists, intensivists, perfusionists, neurologists, educators, primary care physicians, nurses, and physical therapists.

Outcomes should determine primary therapy, and as such must be monitored life-long. This review manuscript will achieve the following objectives:

- Consider the current state of analysis of outcomes of treatments for patients with congenitally malformed hearts,[1–118]
- Lay out some principles which might make it possible to achieve life-long monitoring and follow-up using our databases, and
- Describe the next steps that those involved in the care of these patients need to take in order to achieve these objectives.

The relatively small numbers of patients with congenitally malformed hearts requires multi-institutional cooperation in order to accomplish these goals.

In order to perform meaningful multi-institutional analyses, we suggest that any database must incorporate the following six essential elements:

- Use of a common language and nomenclature[4–40,44,47–51,55,58,62,63,68–71,73,74,76,81–83,89–116]
- Use of a database with an established uniform core dataset for collection of information[1,3,7,8,41,42,44,45,47,48,51–53,58,59,61–63,68,69,71,72,76,78,82,83,85,86,89–116,118]
- Incorporation of a mechanism of evaluating case complexity[2,43,45,46,54,56–58,60,62–65,68,69,75–77,80,82,84,87,99,101,102,117]
- Availability of a mechanism to assure and verify the completeness and accuracy of the data collected[58,62,63,66,67,69,76,82,103]
- Collaboration between medical and surgical subspecialties,[76,82,90,94–97]
- Standardization of protocols for life-long follow-up.[82,88,104,119]

This review article will update and fuse together two prior publications that addressed many of these topics:[76,82]

- Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Gaynor JW, Spray TL, Kurosawa H, Stellin G, Ebels T, Bacha EA, Walters HL, Elliott MJ. 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.
- 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.

Events at Bristol, England,[120] Denver, Colorado,[121–127] and Winnipeg, Canada,[128] have clearly demonstrated the importance of physician-driven analysis of outcomes. For example, the Bristol Report presents the results of the inquiry into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues. Approximately 200 recommendations are made, many of which relate to the need for accurate multi-institutional outcomes databases to quantitate outcomes of care rendered to patients with congenital cardiac disease. Perhaps less well-known than the Bristol Report, the Report of the Manitoba Pediatric Cardiac Surgery Inquest presents data from an inquest involving 12 children who died while undergoing, or soon after having undergone, cardiac surgery at the Winnipeg Health Sciences Centre in 1994. Clearly, these events demonstrate the importance of a meaningful and fair method of multi-institutional analysis of outcomes for congenital cardiac surgery.

Nomenclature

During the 1990s, both The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery created databases to assess the outcomes of congenital cardiac surgery.[8] Beginning in 1998, these two organizations collaborated to create the International Congenital Heart Surgery Nomenclature and Database Project.[6] By 2000, a common nomenclature, along with a common core minimal dataset, were adopted by The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, and published in the Annals of Thoracic Surgery.[6] The system of 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 included both a Short List to facilitate the multi-institutional analysis of outcomes and a Long List to facilitate more detailed coding for electronic medical records and echocardiography software. Five sets of such lists were created:

- Diagnoses
- Procedures
- Preoperative risk factors
- Noncardiac abnormalities
- Complications.

During the same era, The Association for European Paediatric Cardiology published, in Cardiology in the Young, an international system of nomenclature for congenital cardiac disease named the European Paediatric Cardiac Code.[4,5,49,50] The European Paediatric Cardiac Code originated from the anatomical descriptions of Professor Robert Anderson and colleagues, then at the Brompton Hospital in London (and subsequently at The Great Ormond Street Hospital for Children), which culminated in the publication of the Brompton codes in 1985. This nomenclature, with six digit numerical codes, was expanded and developed in the late 1980s by the teams in Utrecht and Leiden in The Netherlands under the auspices of the Dutch Heart Foundation. Rodney Franklin, working in Utrecht, and then at Harefield Hospital in England, revised and extended these codes throughout the 1990s. In 1998, these codes were adopted by The Association for European Paediatric Cardiology, and a Short List was created for usage within databases, with publication of both the Short List and the Long List, inclusive of numerical codes, in 2000.[4,5]

The developers of these two systems of nomenclature view these two diagnostic hierarchies as complementary and not as competitive. Consequently, on Friday October 6, 2000, The International Nomenclature Committee for Pediatric and Congenital Heart Disease was established.[49,50,55] In January, 2005, this International Nomenclature Committee was constituted in Canada as The International Society for Nomenclature of Paediatric and Congenital Heart Disease.

The working component of this international nomenclature society has been The International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Nomenclature Working Group. By 2005, the Nomenclature Working Group crossmapped 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 with the European Paediatric Cardiac Code of the Association for European Paediatric Cardiology, and therefore created the International Paediatric and Congenital Cardiac Code, which is available for free download from the internet at [http://www.IPCCC.NET]. The Nomenclature Working Group has also crossmapped separate systems for coding, and provided unified nomenclature and definitions for several complex congenital cardiac malformations, including the functionally univentricular heart,[70] hypoplastic left heart syndrome,[73] congenitally corrected transposition,[74] and heterotaxy.[81]

The International Paediatric and Congenital Cardiac Code is available free of charge via the Internet at [http://www.IPCCC.NET]. At this Web site, one may download the Short Lists and Long Lists of the International Paediatric and Congenital Cardiac Code. Three versions of the International Paediatric and Congenital Cardiac Code are available:

- 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
- The version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code of The Association for European Paediatric Cardiology
- The version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the Fyler Codes of Boston Children's Hospital and Harvard University.

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 has been utilized in a variety of settings, including the following research studies:

- A multi-institutional study of functionally single ventricle via the Pediatric Heart Network
- The Centers for Disease Control and Prevention birth surveillance research study in which the Metropolitan Atlanta Congenital Defects Program reclassified more than 11,000 patients according to 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.
- A National Institutes of Health grant examining the relationship of air pollution to the development of congenital cardiac malformations in the fetus (R01ES012967)
- The National Institutes of Health-funded multicenter, randomized trial, conducted by the Pediatric Heart Network, that compares outcomes in patients with hypoplastic left heart syndrome (HLHS), or other functionally univentricular hearts of right ventricular morphology, who are randomized to the Norwood Stage 1 Operation with either a modified Blalock-Taussig systemic-to-pulmonary artery shunt or a right ventricle to pulmonary artery ("Sano") shunt. Pediatric Heart Network
- The Pediatric and Congenital Cardiothoracic Surgical Databases under the leadership of The European Association for Cardio-Thoracic Surgery

and The Society of Thoracic Surgeons use 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. Between 1998 and 2007 inclusive, this nomenclature was used by both of these two organizations to analyze outcomes of over 150,000 operations involving patients undergoing surgical treatment for congenital cardiac disease.

In Europe, the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code of The Association for European Paediatric Cardiology has also been utilized in a variety of settings, including the following research studies:

- In the United Kingdom, the United Kingdom Central Cardiac Audit Database uses the Short Lists from the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code as the basis for its national, comprehensive, validated, and benchmark-driven audit of all paediatric surgical and transcatheter procedures undertaken since 2000.
- In Germany, internal quality control for all centres is based on the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code. The Nationale Register fur angeborene Herzfehler in Berlin also uses the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code for coding all patients with congenital heart disease. Additionally the Kompetenznetz angeborene Herzfehler also uses the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code for a nation-wide scientific network supported by the German government for various specific studies, such as on right ventricular function, pulmonary hypertension, tetralogy of Fallot, and interatrial communication.
- In the Netherlands, the national registry of congenital heart disease, CONCOR (Congenital Corvitia), uses the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code.
- The Swiss paediatric cardiology society uses the version of the International Paediatric and Congenital Cardiac Code derived from the nomenclature of the European Paediatric Cardiac Code for quality control between centres.

This common nomenclature, the International Paediatric and Congenital Cardiac Code, is now utilized in multiple subspecialty databases that involve the professionals caring for patients with congenital cardiac disease. Each of these database systems employs the International Paediatric and Congenital Cardiac Code and is at varying stages of development:

- Pediatric and Congenital Cardiothoracic Surgery under the leadership of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons, as well as several national database initiatives such as The United Kingdom Central Cardiac Audit Database (UKCCAD).
- Pediatric and Congenital Cardiology under the leadership of The American College of Cardiology and The Association for European Paediatric Cardiology, as well as several national database initiatives such as The United Kingdom Central Cardiac Audit Database (UKCCAD).
- Pediatric and Congenital Cardiac Anaesthesia under the leadership of The Congenital Cardiac Anesthesia Society
- Pediatric and Congenital Cardiac Critical Care under the leadership of the Pediatric Cardiac Intensive Care Society.

Perhaps the most mature of these databases are the Pediatric and Congenital Cardiothoracic Surgical Databases under the leadership of The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons. These sister databases use the International Paediatric and Congenital Cardiac Code and the common minimum database data set created by the International Congenital Heart Surgery Nomenclature and Database Project and published in the Annals of Thoracic Surgery in April 2000. Between 1998 and 2007, inclusive, this nomenclature and database was used by both of these two organizations to analyze outcomes of over 150,000 operations involving patients undergoing surgical treatment for congenital cardiac disease (Figs 1, 2, 3, and 4).

On Monday July 9, 2007, the International Society for Nomenclature of Paediatric and Congenital Heart Disease created two new committees so that the Society now has the following three committees:

- The International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Nomenclature Working Group
- The International Working Group for Defining the Nomenclatures for Paediatric and Congenital Heart Disease, also known as the Definitions Working Group

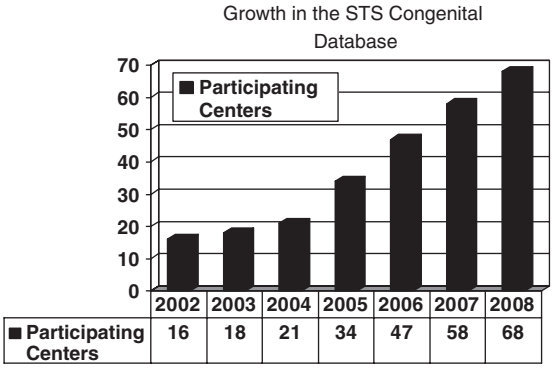


Figure 1.
The graph documents the annual growth in the Congenital Heart Surgery Database of The Society of Thoracic Surgeons by number of participating centres submitting data. The aggregate report from Spring 2008 of the Congenital Heart Surgery Database of The Society of Thoracic Surgeons includes data from 68 Congenital Heart Surgery Centres from the United States of America and Canada. One Japanese centre also submits data; however, these Japanese data are not included in the aggregate report produced by The Society of Thoracic Surgeons.[86]

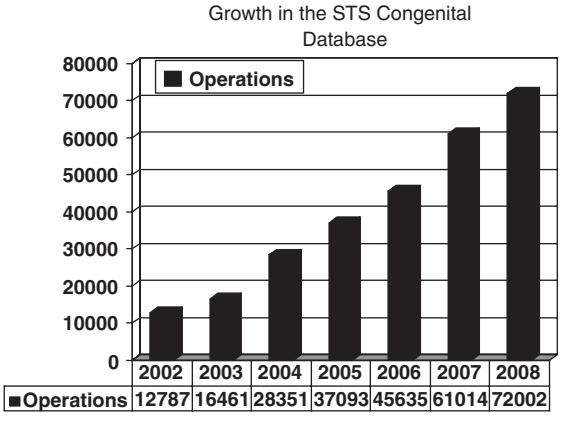


Figure 2.
The graph documents the annual growth in the Congenital Heart Surgery Database of The Society of Thoracic Surgeons by the number of operations per averaged 4 year data collection cycle. The aggregate report from Spring 2008 of the Congenital Heart Surgery Database of The Society of Thoracic Surgeons included data from the four-year window of data harvest beginning January 1, 2004 and ending December 31, 2007, and included 72,002 operations submitted from 68 centres from North America, 67 from the United States of America and 1 from Canada. One Japanese centre also submits data; however, these Japanese data are not included in the aggregate report produced by The Society of Thoracic Surgeons.[86]

- 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, and the Congenital Heart Archiving Research Team.

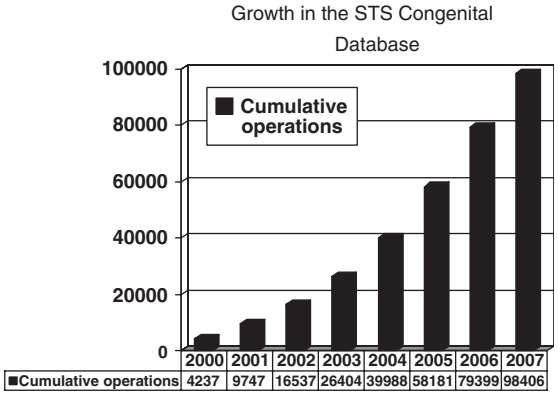


Figure 3.
The graph documents the annual growth in the Congenital Heart Surgery Database of The Society of Thoracic Surgeons by the cumulative number of operations over time. The entire Congenital Heart Surgery Database of The Society of Thoracic Surgeons now contains data from 98,406 operations. The aggregate report from Spring 2008 of the Congenital Heart Surgery Database of The Society of Thoracic Surgeons included data from the four-year window of data harvest beginning January 1, 2004 and ending December 31, 2007, and included 72,002 operations submitted from 68 centres from North America, 67 from the United States of America and 1 from Canada. One Japanese centre also submits data; however, these Japanese data are not included in the aggregate report produced by The Society of Thoracic Surgeons.[86]

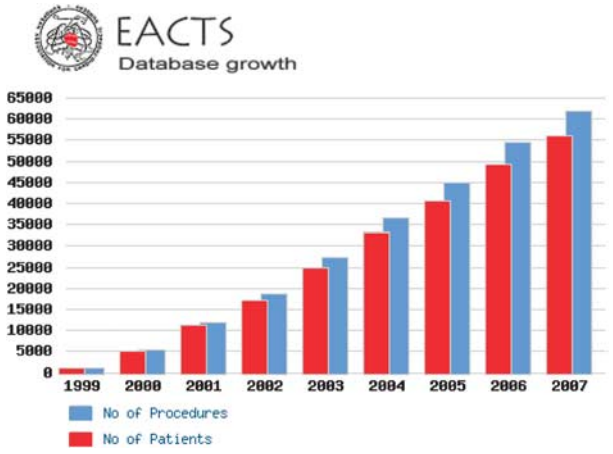


Figure 4.
The graph documents the annual growth in The European Association for Cardio-Thoracic Surgery Congenital Database by both number of patients and number of operations. This graph is provided courtesy of Bohdan Maruszewski of the Children's Memorial Health Institute in Warsaw, Poland, Director of The European Association for Cardio-Thoracic Surgery Congenital Database, and President of The European Congenital Heart Surgeons Association (ECHSA).

The Nomenclature Working Group will continue to maintain, preserve, and update the International Paediatric and Congenital Cardiac Code, as well as provide ready access to it for the international paediatric and congenital cardiology and cardiac

surgery communities, related disciplines, the healthcare industry, and governmental agencies, both electronically and in published form. The Definitions Working Group will write definitions for the terms in the International Paediatric and Congenital Cardiac Code, building on the previously published definitions from the Nomenclature Working Group.[70,73,74,81] The Archiving Working Group will enable the linkage of images and videos to the International Paediatric and Congenital Cardiac Code. The images and videos will be acquired from cardiac morphologic specimens and imaging modalities such as echocardiography, angiography, computerized axial tomography, and magnetic resonance imaging, as well as intraoperative images and videos. An image and video archive will be created, based on the International Paediatric and Congenital Cardiac Code, and this archive will be linked to CTSNet [http://www.ctsnet.org], and the new Congenital Portal of CTSNet [http://www.ctsnet.org/portals/congenital/index.html].

Database standards

The International Paediatric and Congenital Cardiac Code, and the common minimum database dataset created by The International Congenital Heart Surgery Nomenclature and Database Project, are now used by both The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery.[58,63,69] Between 1998 and 2007, inclusive, this nomenclature and database was used by both of these two organizations to analyze outcomes of over 150,000 operations involving patients undergoing surgical treatment for congenital cardiac disease.[76,82] In Table 1, we show data culled from an analysis of over 40,000 patients undergoing surgery in the years 1998 through 2004 inclusive.[69] Multiple publications generated from these two databases have reported outcomes after treatment for congenital cardiac disease in general, as well as outcomes for specific lesions.[58,63,69,85]

The Report of the 2005 Society of Thoracic Surgeons Congenital Heart Surgery Practice and Manpower Survey, undertaken by the Society of Thoracic Surgeons Workforce on Congenital Heart Surgery, documented that 122 centres in the United States of America and 8 centres in Canada perform paediatric and congenital heart surgery.[129] As of June, 2008, the congenital database of the Society of Thoracic Surgeons contains data from 68 of these 130 centres from North America, and is now the largest database in North America dealing with congenital cardiac malformations. It has grown annually since its inception, both in terms of the number of participating centres submitting data, and the number of operations analyzed (Figs 1, 2, and 3). The entire Congenital Heart Surgery Database of The Society of Thoracic Surgeons now contains data from 98,406 operations. The aggregate report from Spring 2008 of the Congenital Heart Surgery Database of The Society of Thoracic Surgeons included data from the four-year window of data harvest beginning January 1, 2004 and ending December 31, 2007, and included 72,002 operations submitted from 68 centres from North America, 67 from the United States of America and 1 from Canada. One Japanese centre also submits data; however, these Japanese data are not included in the aggregate report produced by The Society of Thoracic Surgeons.

By January 1, 2008, the congenital database of The European Association for Cardio-Thoracic Surgery contained 61,750 operations performed in 53,402 patients, including 12,109 operations in neonates, 20,487 in infants, 25,102 in children and 4,052 in adults (Fig. 4). The congenital registry of The European Association for Cardio-Thoracic Surgery grows continuously and recently shows between 5 and 10 thousand new operations each year. 274 Units from 62 countries are registered in the congenital registry of The European Association

Table 1. Aggregated data from the European Association for Cardiothoracic Surgery (EACTS) and the Society of Thoracic Surgeons (STS).[69] The data represent surgical operations performed between 1998 and 2004 inclusive.[41,52,53,69] In this table, each Aristotle Basic Complexity Score is the mean score for the age group and database shown in the table.

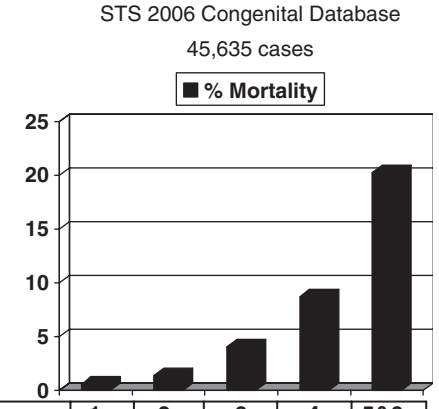
	All	0 to 28 days	29 days to 1 year	Other
STS				
Eligible patients	18,928	3,988	6,152	8,788
Discharge mortality	825	487	202	136
Discharge mortality %	4.4%	12.2%	3.3%	1.5%
Aristotle Basic Complexity Score	7.1	8.6	7.0	6.5
EACTS				
Eligible patients	21,916	4,273	7,316	10,327
Discharge mortality	1,097	514	377	206
Discharge mortality %	5.4%	13.3%	5.56%	2.1%
Aristotle Basic Complexity Score	6.5	7.6	6.6	5.9

for Cardio-Thoracic Surgery and have access to over 300 on-line reports.

Stratification of complexity

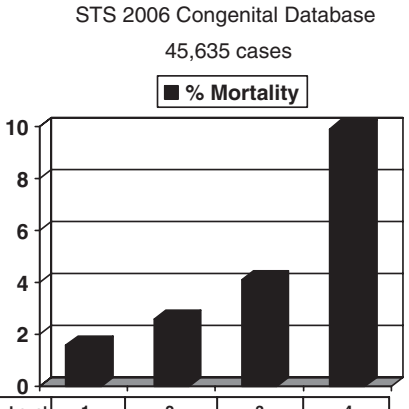
The importance of the quantitation of complexity centres on the fact that, in the field of paediatric cardiac surgery, analysis of outcomes using raw measurements of mortality, without adjustment for complexity, is inadequate. The mix of cases can vary greatly from programme to programme. Without stratification of complexity, the analysis of outcomes will be flawed. Two major multi-institutional efforts that have attempted to measure the complexity of congenital heart surgery are the Risk Adjustment in Congenital Heart Surgery-1 system,[2,45,46,54,60,63,75–77,82,84,99,101,130,131] and the Aristotle Complexity Score.[43,45,56–58,60,62–65,75–77,80,82,84,87,99,101,102,117] The databases of Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery have included the Aristotle Complexity Score in their reports since 2002.[41,52,53,59,72,78,86] In 2006, both databases also incorporated the Risk Adjustment in Congenital Heart Surgery-1 method into their reports.[72,78,86] The Risk Adjustment in Congenital Heart Surgery-1 method has been demonstrated to be a useful tool in several studies in both Europe and North America,[46,54,60,75,130,131] and represents one of the first widely accepted tools for adjustment of complexity developed in our field. Data from The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons multi-institutional databases indicate that the Aristotle Complexity Score correlates well with mortality prior to discharge from the hospital after congenital cardiac surgery, as well as prolonged postoperative length of stay.[43,56,57,60,63–65,80,84]

The 2006 Report of the Congenital Heart Surgery Database of The Society of Thoracic Surgeons included operations performed from 2002 through 2005 inclusive and was the first Database Report of The Society of Thoracic Surgeons to incorporate both the Risk Adjustment in Congenital Heart Surgery-1 system and the Aristotle Complexity Score.[72,77] This 2006 Report included 45,635 submitted operations from 47 North American centres. Overall discharge mortality was 3.9% (1,222/31,719 eligible cardiac index operations). 85.8% (27,202/31,719) of operations were eligible for analysis by the Risk Adjustment in Congenital Heart Surgery-1 system and 94.0% (29,813/31,719) were eligible for analysis by the Aristotle Complexity Score. With both the Risk Adjustment in Congenital Heart Surgery-1 system and Aristotle, as complexity increases, discharge mortality also increases. Figure 5 documents mortality by complexity level using the Risk Adjustment in Congenital Heart Surgery-1 system. Figure 6 documents mortality by complexity level using the Aristotle Complexity Level. The Aristotle Complexity Score allows classification of more operations while the Risk Adjustment in Congenital Heart Surgery-1 system appears to discriminate better at the higher end of complexity. Figure 7 presents the relationship between discharge mortality and the rounded Aristotle Basic Complexity Score. One has the opportunity to stratify operations further, into additional complexity groupings, when the scope of the analysis is expanded beyond



RACHS-1 Level	1	2	3	4	5&6
% Discharge Mortality	0.6%	1.4%	4.1%	8.7%	20.2%
Eligible Operations	3637	10537	8788	2910	1330
Discharge Mortality	23	145	359	252	268

Figure 5.
The graph documents discharge mortality by complexity level using the RACHS-1 system.



Aristotle Basic Complexity Level	1	2	3	4
% Discharge Mortality	1.6%	2.6%	4.1%	9.9%
Eligible Operations	4821	12904	8066	4022
Discharge Mortality	78	330	330	400

Figure 6.
The graph documents discharge mortality by complexity level using the ABC Level.

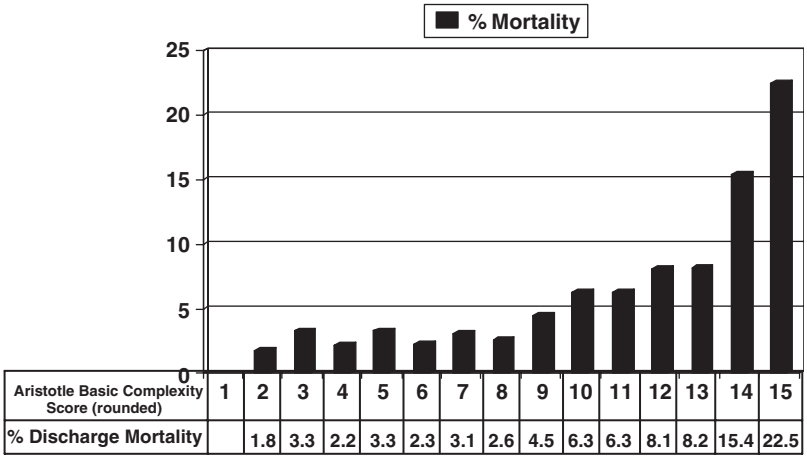


Figure 7.
The graph presents the relationship between discharge mortality and the rounded Aristotle Basic Complexity Score. One has the opportunity to stratify operations further into additional complexity groupings when the scope of the analysis is expanded beyond ABC Level to incorporate ABC Score.

Aristotle Basic Complexity Level to incorporate Aristotle Comprehensive Complexity Score. Efforts are ongoing to develop complexity stratification methodologies that are based more on objective data and less on subjective probability, as well as to unify the RACHS-1 system and the Aristotle Complexity Score.

Verification of data

The need exists for a common methodology to be developed and implemented to verify the data submitted to all registries worldwide that analyze the outcomes of treatments for patients with congenitally malformed hearts. Common definitions must be used for fields related to mortality and morbidity.[71,83] Verification of the completeness of the data is crucial because it has been previously shown that patients not included in medical audit have a worse outcome than those included.[132] In a multi-institutional database of vascular surgery tracking all infrainguinal bypass operations at involved institutions, independent audit revealed that sixteen per cent of eligible cases had not been reported. Mortality and the rate of amputation were twice as high among the missing cases as among the reported cases; however, no difference in patency was identified between the missing cases and the reported cases. The authors concluded that "Overall judgement of the performance of an individual department may be impaired by cases not included in the register." [132]

The importance of the verification of the accuracy of the data is demonstrated by a recent prospective, longitudinal, observational, national cohort survival study from the United Kingdom Central Cardiac Audit Database.[133] This analysis included 3,666 surgical procedures and 1,828 therapeutic catheterizations performed from 2000 and 2001, in all 13 tertiary centres in the United Kingdom performing cardiac surgery or therapeutic cardiac catheterization in children with congenital cardiac disease. Deaths within 30 days of the procedure were established both by results volunteered from the hospital databases, and by independently validated records of deaths obtained by the Office for National Statistics, using the patient's unique National Health Service number, or the general register offices of Scotland and Northern Ireland. Central tracking of mortality identified 469 deaths, with 194 occurring within 30 days and 275 later. Of the 194 deaths occurring within 30 days, 42, or 21.6%, were detected by central tracking but not by volunteered data. In other words, hospital-based databases underreported mortality within 30 days of the procedure by 21.6%, even though the hospitals were aware that the data would be independently verified. The authors of the report concluded that "independent data validation is essential for accurate survival analysis" and that "one-year survival gives a more realistic view of outcome than traditional perioperative mortality".[133] These two publications[132,133] clearly demonstrate the importance of verification of data for both completeness and accuracy.

The European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Database[66,67] attempted to verify the data within the databases of five European centres utilizing "source data verification". Pre-verification and post-verification mortalities in all groups showed no significant differences, although 7 deaths out of 68 (10.27%) were missed. None of the other verified fields showed significant

differences after verification. The authors stated that "source data verification" showed no statistically significant differences between verified and nonverified data on mortality at 30 days after surgery, length of stay in the hospital, age, body weight, cardiopulmonary bypass time, aortic cross-clamp time, and circulatory arrest time. The authors also state that "an international committee of experts is needed to define common data verification methodology and to apply it in future works on outcome analysis in CHS (congenital heart surgery)." This study[66] analyzes the data properly, and appropriately discusses the limitations of the analysis.[67,76] The authors candidly report that one-tenth of deaths were missed. This presentation of the "missed mortality" data is more honest than stating that 7 deaths out of 1,895 operations, or 0.37 percent, were missed. Although the authors state that "source data verification" showed no statistically significant differences between verified and nonverified data in the field of mortality 30 days after surgery, it is troubling that one-tenth of these deaths were not reported. This study confirms the need for a common methodology for verification of data to be developed and implemented in all registries collecting outcomes worldwide. Common definitions for fields related to mortality and morbidity have been implemented into these registries.[71,83,92] These common definitions will need to be maintained in order to facilitate optimal verification of data.

Collaborative efforts involving The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons continue with the goal of developing improved mechanisms to verify the completeness and accuracy of the data in the databases.[76,82,103] Both The European Association for Cardio-Thoracic Surgery,[66,67,103] and the Society of Thoracic Surgeons,[103] utilize a program of site visits for onsite verification of data. Data in these databases are verified through both an intrinsic data verification process designed to rectify inconsistencies of data and missing elements of data, as well as an on-site audit program with verification of the data at the primary source of the data. A combination of three strategies may ultimately be required to allow for optimal verification of data:

- Intrinsic data verification (designed to rectify inconsistencies of data and missing elements of data)
- Site visits with "Source Data Verification" (in other words, verification of the data at the primary source of the data)
- External verification of the data from independent databases or registries (such as governmental death registries)

Further research in the area of verification of data is necessary. Data must be verified for both completeness and accuracy.[76,82,103]

Collaboration between medical and surgical subspecialties

Further collaborative efforts are ongoing between paediatric and congenital cardiac surgeons and other subspecialties, including paediatric cardiac anaesthesiologists, via The Congenital Cardiac Anesthesia Society, paediatric cardiac intensivists, via The Pediatric Cardiac Intensive Care Society, and paediatric cardiologists, via the Joint Council on Congenital Heart Disease and The Association for European Paediatric Cardiology. The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease has been created to foster these collaborative efforts and is composed of members of the following organizations:[76,82]

- The Society of Thoracic Surgeons Congenital Database Taskforce
- The Society of Thoracic Surgeons Congenital Database Taskforce Core Users Group
- The Society of Thoracic Surgeons Congenital Database Data Verification Subcommittee
- The European Association for Cardio-Thoracic Surgery Congenital Heart Committee
- The Aristotle Institute, developers of the Aristotle Complexity Score
- The Multi-Center Panel of Experts for Cardiac Surgical Outcomes, developers of the Risk Adjustment in Congenital Heart Surgery-1 system
- The Pediatric Cardiac Intensive Care Society VPS Database
- The Congenital Cardiac Anesthesia Society
- The Joint Council on Congenital Heart Disease
- The Association for European Paediatric Cardiology
- The Pediatric Committee of the International Consortium of Evidence Based Perfusion
- The International Working Group for Mapping and Coding of Nomenclatures for Paediatric and Congenital Heart Disease, otherwise known as the Nomenclature Working Group
- The World Society for Pediatric and Congenital Heart Surgery
- The Center for Quality Improvement and Patient Safety of Agency for Healthcare Research and Quality of the United States Department of Health and Human Services of the United States of America
- The Birth Defect Branch of the Centers for Disease Control and Prevention of the United States of America.

Under the leadership of The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, multiple ongoing collaborative initiatives include:

- Developing regional outcomes reporting initiatives
- Developing improved methodologies of data verification, utilizing site visits with source data verification and perhaps linking to the Social Security Death Master File in the United States
- Validating the Aristotle Basic Complexity Score
- Unifying the Aristotle Basic Complexity Score and the Risk Adjustment for Congenital Heart Surgery methodology
- Developing improved methodologies to assess and measure morbidity
- Developing improved methodologies of long term follow-up
- Improving the level of national and international database participation
- Increasing the involvement from Africa, Asia, Australia and Oceania, and South America.

The preparation 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" under the leadership of The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease exemplifies the benefits of collaboration between medical and surgical subspecialties.

Future initiatives – can we do better?

A great deal has already been accomplished to standardize and improve methodologies for the analysis of outcomes following the treatment of patients with congenital cardiac disease. While these achievements have laid the groundwork, much remains to be accomplished. We can, and should, rise to the challenge, by more effectively defining and measuring outcomes, setting standards to benchmark results, and using these data to change and improve upon our current practice and these results. A non-comprehensive listing of areas in need of improvement includes:

- Standardizing and unifying the tools for stratification of complexity
- Improving the tools for stratification of complexity so that these tools are based more on objective data and less on subjective probability
- Improving the tools for stratification of complexity in order to account for patient-specific variables
- Creating methodologies for analysis beyond mortality as an endpoint
- Defining morbidity and complications
- Improving methodologies for verification of data
- Clarifying the relationship between administrative databases and clinical databases
- Developing and implementing unique identifiers of all patients, compliant with The Health Insurance Portability and Accountability Act of the federal government of the United States of America
- Establishing links between databases
- Moving beyond geographical barriers
- Moving beyond subspecialty barriers
- Standardizing long term follow-up, including modules for collection of this data
- Identifying non-traditional sources of funding for collection, entry, and verification of data, as well as real time statistical analyses.

Standardizing and unifying the tools for stratification of complexity

Current efforts to unify the Risk Adjustment in Congenital Heart Surgery-1 system and the Aristotle Complexity Score are in their early stages, but encouraging.[76,77,82] Both tools for stratification of complexity are slightly different, and each is only an approximation of stratification of complexity, and not true risk-adjustment. With both systems, as complexity increases, mortality prior to discharge from the hospital also increases.[77] The Aristotle methodology allows classification of more operations, while the Risk Adjustment in Congenital Heart Surgery-1 system discriminates better at the higher end of complexity.[77] The developers of both systems feel that time and effort spent comparing these two systems are better spent improving overall outcomes for patients with congenitally malformed hearts. Efforts are already underway, involving the developers of each system, to unify these two systems so as to capitalize on the strengths of each. This new combined index of mortality will include elements of both methods, will be based on objective, observed data whenever it is available, and will limit the use of subjective probability, or expert opinion, to areas where objective data is lacking.

Improving the tools for stratification of complexity so that these tools are based more on objective data and less on subjective probability

In the past, methods of complexity stratification were developed based primarily on subjective probability, or expert opinion, because objective data was lacking or unavailable. The rapid growth of our databases will allow for the development and implementation of more sophisticated methodologies of complexity stratification based more on objective data.[102,117]

Improving the tools for stratification of complexity in order to account for patient specific-variables

Neither the Risk Adjustment in Congenital Heart Surgery-1 system nor the Aristotle Basic Complexity Score incorporate detailed patient-specific risk factors into their algorithms. The Aristotle Comprehensive Complexity Score adds to the Aristotle Basic Complexity Score by incorporating two sorts of patient-specific modifiers of complexity:

- Procedure Independent Factors
- Procedure Dependent Factors.

"Procedure Independent Factors" include general factors, clinical factors, extracardiac factors, and surgical factors. "Procedure Dependent Factors" include anatomical factors, associated procedures, and age at procedure. The Aristotle Committee is currently involved in ongoing research to validate the Aristotle Comprehensive Complexity Score on a multi-institutional basis.

Creating methodologies for analysis beyond mortality as an endpoint

In the databases of both The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery, mortality prior to discharge from the hospital is now between 4% and 5%. In order to evaluate the quality of care delivered to the remaining 95% to 96% of patients, parameters must be developed and standardized that will allow the analysis of the outcomes of these surviving patients. This analysis will require standardization of measurements for morbidity, complications, quality of life, long term survival, and functional status. These standards must then be implemented into our databases. The definitions provided in this Supplement to Cardiology in the Young, as well as those provided in other similar publications,[71,83] will help accomplish this objective.

Defining morbidity and complications

Under the leadership of The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, this Supplement provides a "Universal Dictionary for Definitions of Complications Associated with the Treatment of Patients with Congenital Cardiac Disease". Supported by a grant from the Children's Heart Foundation, this multi-disciplinary project will move toward standardization of the definitions of complications and morbidity. This group has already offered multiple definitions,[83,92] four of which are presented below:

- Morbidity is defined as "a state of illness or lack of health, and includes physical, mental, or emotional disability"
- A complication is defined as "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 medical error is defined as "a health care intervention, that may be an act of commission or omission, where a planned action fails to be completed as intended or the use of a wrong plan is implemented to achieve an aim; this event is a departure from the desired course of events, is less than ideal, and may cause or be associated with suboptimal outcome"
- An adverse event is defined as "a complication that is associated with a healthcare intervention and is associated with suboptimal outcome".

Improving methodologies for verification of data

Collaborative efforts involving The European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons continue with the goal of developing improved mechanisms to verify the completeness and accuracy of the data in the databases.[76,82,103] Ideally, standardized methodologies of verification of data will be used by all databases and registries in all geographical regions and subspecialty societies. The independent verification of life or death from national registries of death can enhance efforts at verification of data. In the United Kingdom, the United Kingdom Central Cardiac Audit Database verifies deaths with independently validated records of deaths obtained by the Office for National Statistics, using the patient's unique National Health Service number, or the general register offices of Scotland and Northern Ireland. In the United States, early efforts are underway to perform similar verification in the Databases of The Society of Thoracic Surgeons using the Social Security Death Master File, also known as the Social Security Death Index, with potential eventual utilization of the National Death Index of the United States in the future. The science of verification of data is a field that can benefit from collaboration that goes beyond traditional subspecialty and geographical boundaries. The value of our databases depends on data that is verified to be complete and accurate.

Clarifying the relationship between administrative databases and clinical databases

The Congenital Database Task Force of The Society of Thoracic Surgeons advocates the use of clinical databases rather than administrative databases for the evaluation of quality of care for patients undergoing treatment for congenital cardiac disease.

Evidence from three recent investigations suggests that the validity of coding of lesions seen in the congenitally malformed heart via the International Classification of Diseases as used in administrative databases is likely to be poor.[93,134,135] First, in a series of 373 infants with congenital cardiac defects at Children's Hospital of Wisconsin, investigators report that only 52% of the cardiac diagnoses in the medical records had a corresponding code from the International Classification of Diseases in the hospital discharge database.[134] Second, the Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with a code for congenital cardiac disease using the International Classification of Diseases. A review of these 66 medical records by physicians was able to confirm only 41% of the codes contained in the administrative database from the International Classification of Diseases.[135] Third, the Metropolitan Atlanta Congenital Defect Program of the Birth Defect Branch of the Centers for Disease Control and Prevention of the federal government of the United States of America carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003.[93] These records were reviewed and classified using both administrative coding and the clinical nomenclature used in the Society of Thoracic Surgeons Congenital Heart Surgery Database. This study concluded that analyses based on the codes available in the International Classification of Diseases are likely to "have substantial misclassification" of congenital cardiac disease. Results from this collaborative study, involving the Metropolitan Atlanta Congenital Defect Program of the Birth Defect Branch of the Centers for Disease Control and the Congenital Database Task Force of The Society of Thoracic Surgeons, are published in a separate manuscript in this Supplement.[93]

Several potential reasons can explain the poor diagnostic accuracy of administrative databases and codes from the International Classification of Diseases:

- accidental miscoding
- coding performed by medical records clerks who have never seen the actual patient
- contradictory or poorly described information in the medical record
- lack of diagnostic specificity for congenital cardiac disease in the codes of the of International Classification of Diseases
- inadequately trained medical coders.

Ongoing collaborative research under the leadership of The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, involving both the Agency for Healthcare Research and Quality, and the Centers for Disease Control and Prevention, should clarify further the relationship between administrative databases and clinical databases. The data within administrative databases and clinical databases may truly be complementary. By linking these administrative and clinical databases together, it may be possible to enhance our ability to perform analysis of outcomes, longitudinal follow-up, and even the assessment of healthcare economics.[82,88,104]

Developing and implementing unique identifiers of all patients, compliant with The Health Insurance Portability and Accountability Act of the federal government of the United States of America

In 1996, the Health Insurance Portability and Accountability Act was enacted by the Congress of the United Stated of America.[136] Title I of this legislation protects health insurance coverage for workers and their families when they change or lose their jobs. Title II of this legislation, the Administrative Simplification provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The Administrative Simplification provisions also address the security and privacy of health data, with the goal of improving the efficiency and effectiveness of the nation's health care system by encouraging the widepread use of electronic data interchange. The Privacy Rule, that took effect on April 14, 2003, established regulations for the use and disclosure of Protected Health Information, which is any information about the state of health, provision of health care, or payment for health care that can be linked to an individual. Protected Health Information is interpreted rather broadly and includes any part of a payment history or medical record of the patient.[136]

Although the Health Insurance Portability and Accountability Act is law only in the United States of America, many nations have enacted similar legislation, or will do so in the future. An understanding of this law and its relationship to the incorporation of unique identifiers of patients into a multi-institutional database will therefore likely play a role in many countries. The congenital databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery currently do not include such unique patient identification. Information allowing for the identification of individual patients needs to be included in multi-institutional databases to facilitate the following objectives:

- The multi-institutional database would be able to verify mortality data with state-wide, regional, and national death registries such as the United States National Death Index

- The multi-institutional surgical database would be able to share data with other subspecialty databases like the databases of the American College of Cardiology, the Congenital Cardiac Anesthesia Society, the Pediatric Cardiac Intensive Care Society, the Extracorporeal Life Support Organization, and the Pediatric Heart Transplant Study Group
- The multi-institutional database would be able to link and follow patients when they have multiple operations in different institutions, a common occurrence in congenital cardiac surgery
- The Society of Thoracic Surgeons Database would be able to link and follow patients who have had operations in more than one of their three databases: Adult Cardiac Surgery, Adult Thoracic Surgery, and Congenital Heart Surgery
- The multi-institutional database would be able to perform long term follow-up and generate Kaplan-Meier Survival curves from the data.

It is possible to incorporate unique patient identification into a multi-institutional database and remain compliant with the Health Insurance Portability and Accountability Act and similar legislation.[88] Unique patient identification used for initiatives to improve quality and related incidental research can be maintained in a compliant fashion by using several data protective strategies.[88]

As cardiothoracic surgeons, one of our professional responsibilities is the longitudinal follow-up of patients undergoing cardiothoracic surgery. The Database of The Society of Thoracic Surgeons is the largest clinical cardiothoracic surgical database in North America and currently includes (as of August 8, 2008) 1,111 participating sites with 3,273 participating surgeons.[88]

- Adult Cardiac Surgery Database: Participants = 931, Surgeons = 2,735, greater than 3 million operations;
- General Thoracic Surgery Database Participants = 108, Surgeons = 365, Operations = 87,987;
- Congenital Heart Surgery Database Participants = 72, Surgeons = 173, Operations = 98,406.

Presently, the Databases of The Society of Thoracic Surgeons provide only in-hospital and 30-day follow-up of patients. Recognizing the critical importance of long-term follow-up, the Workforce on National Databases of The Society of Thoracic Surgeons has initiated a strategy to facilitate longitudinal follow-up of patients in the Database. A key element of this strategy entails the use of specific identifiers that will permit long-term tracking of important patient events. Accordingly, on January 1, 2008, the Adult Cardiac Surgery Database of The Society of Thoracic Surgeons began collecting Unique Patient, Surgeon, and Hospital Identifier Fields that are compliant with the Health Insurance Portability and Accountability Act. Similar Identifier Fields will be added to the General Thoracic Surgery Database of The Society of Thoracic Surgeons on January 1, 2009, and to the Congenital Heart Surgery Databases of The Society of Thoracic Surgeons on January 1, 2010 (Tables 2 and 3).

Establishing links between databases

Developing useful links between different multi-institutional databases requires two accomplishments:

- Standardization of nomenclature, definitions, and terminology
- Incorporation of unique patient identification into the multi-institutional database.

These links between databases will then lead to multiple benefits in the areas of data verification, subspecialty collaboration, and long term follow-up, as described above and below.

Moving beyond geographical barriers

As documented by this review, the current initiatives, concerning databases designed to analyze outcomes of the treatment of patients with congenitally malformed hearts, are dominated by projects in Europe and North America. As we move forward, it will be crucial to extend beyond traditional geographical barriers, and increase the involvement from Africa, Asia, Australia and Oceania, and South America. The newly formed World Society for Pediatric and Congenital Heart Surgery lists as one of its primary objectives "To organize and maintain a global database on operations and outcomes built upon extant continental databases."[137] The globalization of these efforts is certainly an area where "we can do better."

Moving beyond subspecialty barriers

As this review also documents, with the exception of the United Kingdom Congenital Cardiac Audit Database, the current initiatives, concerning databases designed to analyze outcomes of the treatment of patients with congenitally malformed hearts, are dominated by surgeons. Under the leadership of The MultiSocietal Database Committee for Pediatric and Congenital Heart Disease, multiple ongoing collaborative projects exist, with the ultimate objective of increasing involvement, in these initiatives and databases, of paediatric cardiac anaesthesiologists, paediatric cardiac intensivists, and paediatric cardiologists. The Society of Thoracic Surgeons Congenital Database Taskforce and The Pediatric Cardiac Intensive Care Society have had

Table 2. Identifiers for the STS Adult Cardiac Surgery Database and Adult Thoracic Database

		Data Specifications Adult Cardiac Data Version 2.52.1			Data Specifications Adult Cardiac Data Version 2.61		
	Field	**Short Name**	**Seq. No.**	**Note**	**Short Name**	**Seq. No.**	**Data definition**
Hospital Identifier	Hospital Name	HospName	220		HospName	220	Indicate the full name of the facility where the procedure was performed. Values should be full, official hospital names with no abbreviations or variations in spelling for a single hospital. Values should also be mixed-case.
	Hospital Zip Code	HospZip	230		HospZIP	230	Indicate the ZIP code of the hospital. Outside the USA, these data may be known by other names such as Postal Code (needing 6 characters). Software should allow sites to collect up to 10 characters to allow for Zip+4 values. This field should be collected in compliance with state/local privacy laws.
	Hospital State	HospStat	240		HospStat	240	Indicate the abbreviation of the state or province in which the hospital is located.
	Hospital National Provider Identifier	NA			HospNPI	241	Indicate the hospital's National Provider Identification (NPI). This number, assigned by the Center for Medicare and Medicaid Services (CMS), is used to uniquely identify facilities for Medicare billing purposes.
Surgeon/Group Identifiers	Surgeon Name	Surgeon	1210		Surgeon	1210	Indicate the surgeon's name. This field must have controlled data entry where a user selects the surgeon name from a user list. This will remove variation in spelling, abbreviations and punctuation within the field.
	Surgeon National Provider Identifier	NA			SurgNPI	1221	Indicate the individual-level National Provider Identifier of the surgeon performing the procedure.
	Referring Cardiologist Name	RefCard	200	Not harvested	RefCard	200	Indicate the referring cardiologist's name.
	Referring Physician Name	RefPhys	210	Not harvested	RefPhys	210	Indicate the referring physician's name.
	Taxpayer Identification Number	NA			TIN	1222	Indicate the group-level Taxpayer Identification Number for the Taxpayer holder of record for the Surgeon's National Provider Identifier that performed the procedure.
Patient Identifiers	Patient First Name	PatFName	110	Not harvested	PatFName	110	Indicate the patient's first name documented in the medical record. This field should be collected in compliance with state/local privacy laws.
	Middle Initial	PatMInit	120	Not harvested	PatMInit	120	Indicate the patient's middle initial documented in the medical record. Leave "blank" if no middle name. This field should be collected in compliance with state/local privacy laws.
	Last Name	PatLName	100	Not harvested	PatLName	100	Indicate the patient's last name documented in the medical record. This field should be collected in compliance with state/local privacy laws.

Table 2. *Continued*

Social Security Number	SSN	160	Not harvested. Definition=Indicate the nine-digit patient's Social Security Number (SSN). Although this is the Social Security Number in the USA, other countries may have a different National Patient Identifier Number. For example in Canada, this would be the Social Insurance Number.	SSN	160	Indicate the nine-digit patient's Social Security Number (SSN). Although this is the Social Security Number in the USA, other countries may have a different National Patient Identifier Number. For example, in Canada, this would be the Social Insurance Number. This field should be collected in compliance with state/local privacy laws.
Medical Record Number	MedRecN	170	Not harvested. Definition=Indicate the patient's medical record number at the hospital where surgery occurred	MedRecN	170	Indicate the patient's medical record number at the hospital where surgery occurred. This field should be collected in compliance with state/local privacy laws. (Begin harvesting as 'harvest optional')
Date of Birth	DOB	130	Harvest optional	DOB	130	Indicate the patient's date of birth using 4-digit format for year. This field should be collected in compliance with state/local privacy laws.
Health Insurance Claim (HIC) Number	NA			HICNumber	171	Indicate the Health Insurance Claim (HIC) number of the primary beneficiary. This is an 11-digit number that uniquely identifies an individual for a claim. (The HIC number consists of the Social Security Number and an alpha-numeric identifier. This identifier is usually just one digit [but in few instances may be two digits]. There may be only 10 digits to enter. It is the number found on patient's Medicare cards. If the patient is not a Medicare patient, they will not have a HIC number.)

Table 3. Identifiers for the STS Congenital Heart Surgery Database

	Field	Short Name	Data definition
Hospital Identifier	Hospital Name	HospName	Indicate the full name of the facility where the procedure was performed. Values should be full, official hospital names with no abbreviations or variations in spelling for a single hospital. Values should also be mixed-case.
	Hospital Zip Code	HospZIP	Indicate the ZIP code of the hospital. Outside the USA, these data may be known by other names such as Postal Code (needing 6 characters). Software should allow sites to collect up to 10 characters to allow for Zip+4 values. This field should be collected in compliance with state/local privacy laws.
	Hospital State	HospStat	Indicate the abbreviation of the state or province in which the hospital is located.
	Hospital National Provider Identifier	HospNPI	Indicate the hospital's National Provider Identification (NPI). This number, assigned by the Center for Medicare and Medicaid Services (CMS), is used to uniquely identify facilities for Medicare billing purposes.
Surgeon/Group Identifiers	Surgeon Name	Surgeon	Indicate the surgeon's name. This field must have controlled data entry where a user selects the surgeon name from a user list. This will remove variation in spelling, abbreviations and punctuation within the field.
	Surgeon National Provider Identifier	SurgNPI	Indicate the individual-level National Provider Identifier of the surgeon performing the procedure.
	Referring Cardiologist Name	RefCard	Indicate the referring cardiologist's name.
	Referring Physician Name	RefPhys	Indicate the referring physician's name.
	Resident	Resident	
	Resident ID	ResidentID	
	Assistant Surgeon	AsstSurgeon	
	Assistant Surgeon ID	AsstSurgeonID	
	Consulting Attendant	CnsltAttnd	
	Consulting Attendant ID	CnsltAttndID	
	Taxpayer Identification Number	TIN	Indicate the group-level Taxpayer Identification Number for the Taxpayer holder of record for the Surgeon's National Provider Identifier that performed the procedure.
Patient Identifiers	Patient First Name	PatFName	Indicate the patient's first name documented in the medical record. This field should be collected in compliance with state/local privacy laws.
	Middle Initial	PatMInit	Indicate the patient's middle initial documented in the medical record. Leave "blank" if no middle name. This field should be collected in compliance with state/local privacy laws.
	Last Name	PatLName	Indicate the patient's last name documented in the medical record. This field should be collected in compliance with state/local privacy laws.
	Social Security Number	SSN	Indicate the nine-digit patient's Social Security Number (SSN). Although this is the Social Security Number in the USA, other countries may have a different National Patient Identifier Number. For example, in Canada, this would be the Social Insurance Number. This field should be collected in compliance with state/local privacy laws.
	Medical Record Number	MedRecN	Indicate the patient's medical record number at the hospital where surgery occurred. This field should be collected in compliance with state/local privacy laws. (Begin harvesting as 'harvest optional')
	Date of Birth	DOB	Indicate the patient's date of birth using 4-digit format for year. This field should be collected in compliance with state/local privacy laws.
	City of Birth	BirthCit	City in which the patient was born.
	State of Birth	BirthSta	State in which the patient was born. Synchronize with state variables in Adult 2.6 – i.e. use of Province as an option.
	Country of Birth	BirthCou	Country in which patient was born.
	Mother's First Name	MatFName	First name of patient's biological mother at time of patient's birth.
	Mother's Middle Initial	MatMInit	Middle initial of patient's biological mother at time of patient's birth.
	Mother's Last Name	MatLName	Last name of patient's biological mother at time of patient's birth.
	Mother's Social Security Number	MatSSN	Social Security Number of patient's biological mother.
	Health Insurance Claim (HIC) Number	HIC	**Indicate the Health Insurance Claim (HIC) number of the primary beneficiary. This is an 11-digit number that uniquely identifies an individual for a claim. NOTE: THIS VARIABLE ONLY TO BE**

Table 3. *Continued*

	CONSIDERED IF REQUIRED BY CMS FOR PAY FOR PERFORMANCE. This is an 11-digit number that uniquely identifies an individual for a claim. It consists of the HIC number of the primary beneficiary plus a modifier to determine the relationship of the patient to the beneficiary. This number will likely be required for the CMS pay for performance project. NOTE: That this Medicare ID number sometimes does change through time as in the case of someone getting married and getting their insurance through spouse. CMS does not provide HIC anymore in its research identifiable files so this variable would not help linking to CMS data for longitudinal follow-up. **NOTE**: This variable might not be useful for the congenital database in the current context of Medicare, but it might be useful in the context of Medicaid. (The HIC number consists of the Social Security Number and an alpha-numeric identifier. This identifier is usually just one digit [but in few instances may be two digits]. There may be only 10 digits to enter. It is the number found on patient's Medicare cards. If the patient is not a Medicare patient, they will not have a HIC number.)

several meetings. The Pediatric Cardiac Intensive Care Society utilizes a database known as the VPS system (the Virtual PICU System). The Pediatric Cardiac Intensive Care Society has agreed to map its coding system to the International Paediatric and Congenital Cardiac Code and this project is near completion. Efforts are also being explored to link the Congenital Database of The Society of Thoracic Surgeons to the VPS system of the Pediatric Cardiac Intensive Care Society. The Congenital Cardiac Anesthesia Society has also agreed to utilize the International Paediatric and Congenital Cardiac Code in its database and has begun to develop a joint "Congenital Cardiac Anesthesia Society – Society of Thoracic Surgeons Congenital Database". The Joint Council on Congenital Heart Disease is developing a project using a database of paediatric cardiology that will also utilize the International Paediatric and Congenital Cardiac Code. The American College of Cardiology has initiated the development of a Database of Congenital Cardiology named "IMPACT", which stands for "IMproving Pediatric and Adult Congenital Treatment". The IMPACT Database will also utilize the International Paediatric and Congenital Cardiac Code. Members of the Congenital Database Taskforce of The Society of Thoracic Surgeons are collaborating with the American College of Cardiology as this database is developed. Goals include harmonization of definitions and linking of datasets.

All of these collaborative efforts will be integral to achieve the ultimate goal of developing a multi-institutional outcomes database that allows long-term follow-up. In the end, we should strive to develop a seamless database that spans geographical and subspecialty boundaries and effortlessly links multiple databases including those shown in the following non-comprehensive listing:

- The Database of The Society of Thoracic Surgeons [http://www.sts.org/]
- The Database of The European Association for Cardio-Thoracic Surgery [http://www.eacts.org/]
- The Database of The Congenital Heart Surgeons' Society (CHSS) [http://www.chss.org/]
- The IMPACT Database of The American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) [http://www.ncdr.com/WebNCDR/Common/] (NCDR® is an initiative of the American College of Cardiology Foundation®, with partnering support from the following organizations: ACTION Registry®–GWTG™–American Heart Association; CARE Registry®–The Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, American Academy of Neurology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and Society for Vascular Medicine; CathPCI Registry®–The Society for Cardiovascular Angiography and Interventions; ICD Registry™–Heart Rhythm Society.)
- The Database of The Joint Council on Congenital Heart Disease [http://www.aap.org/sections/cardiology/JCCHD.htm] (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.)

- Databases associated with The Association For European Paediatric Cardiology [http://www.aepc.org/aepc/nid/Home]
- The Central Cardiac Audit Database of the United Kingdom [http://www.ccad.org.uk/congenital]
- The Database of Congenital Cardiac Anesthesia Society [http://www.pedsanesthesia.org/ccas/] (The Congenital Cardiac Anesthesia Society (CCAS) is a new Society organized within the Society for Pediatric Anesthesia. The concept of the Congenital Cardiac Anesthesia Society originated with directors of cardiac anaesthesia and other key leaders at major congenital cardiac disease programs, who believed there was a need for a new society because of rapid advancement of highly specialized knowledge in the field, and a great increase in the numbers of patients, including adults with congenital cardiac disease. Part of the mission of the Congenital Cardiac Anesthesia Society is organizing and maintaining a multi-institutional database of the anaesthetic care of patients with congenital cardiac disease.)
- The VPS Database of The Pediatric Cardiac Intensive Care Society [https://portal.myvps.org/default.aspx] (The VPS system [The Virtual PICU System] is a clinical database dedicated to standardized sharing of data and benchmarking among paediatric intensive care units. All participants collect information on patient and hospital stay measures, diagnoses, interventions, discharge, organ donation, and paediatric severity of mortality scores. Users can choose to collect data for multi-site research studies and additional internal research needs through customizable interfaces.)
- The Extracorporeal Life Support Organization (ELSO) Registry[http://www.elso.med.umich.edu/] (The Extracorporeal Life Support Organization (ELSO) is an international consortium of health care professionals and scientists who are dedicated to the development and evaluation of novel therapies for support of failing organ systems. Crucial is the promotion of a broad multidisciplinary collaboration. The primary mission of the Organization is to maintain a registry of, at least, use of extracorporeal membrane oxygenation in active ELSO centres. As appropriate, registries of other novel forms of organ system support are within the purview of ELSO. Registry data is to be used to support clinical research, support regulatory agencies, and support individual ELSO centres. ELSO provides educational programs for active centres as well as for the broader medical and lay communities.)
- The Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS Registry) [http://www.intermacs.org/] (INTERMACS is a national registry in the United States of America for patients who are receiving mechanical circulatory support device therapy to treat advanced cardiac 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).
- The cardiac transplantation Database of the Pediatric Heart Transplant Study Group [http://www.ingentaconnect.com/content/bsc/chd/2006/00000001/00000003/art00002] (The Pediatric Heart Transplant Study (PHTS) group was founded in 1991 as a voluntary, collaborative effort dedicated to the advancement of the science and treatment of children following listing for heart transplantation. Since 1993, the PHTS has collected data in an international, prospective, event-driven database that examines risk factors for outcome events following listing for transplantation. The events include transplantation, death, rejection, infection, malignancy, graft vasculopathy, and retransplantation. Over its 17 years of existence, the Pediatric Heart Transplant Study Group has made major contributions to the field of paediatric heart transplantation, especially in the areas of analysis of outcomes and assessment of risk factors for death and other major morbidities after listing and after transplantation. The new challenges facing the Pediatric Heart Transplant Study Group include how to implement the practice of

evidence-based medicine in the field of paediatric heart transplantation and how to support ongoing data collection and analysis to provide long-term outcomes as the Pediatric Heart Transplant Study Group subjects enter their second decade after transplantation.)

Standardizing long term follow-up, including modules for collection of this data

Standardizing long-term follow-up is the key to the future of the discipline, and yet it remains thoroughly undeveloped! The databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery currently do not allow for long-term follow-up. At the present time, the period of collection of data for these databases ends when both of the following two criterions have been satisfied:[71,83]

- the patient has been discharged from the hospital after the operation
- 30 days have passed since the operation.

Thus, if a patient is discharged home prior to 30 days after surgery, data is collected until 30 days have passed since the operation. Furthermore, if a patient is still in the hospital after 30 days have passed since the operation, data is collected until discharge from the hospital.

As stated earlier, analysis of outcomes must move beyond mortality, and encompass longer term follow-up, including cardiac and non cardiac morbidities, and importantly, those morbidities impacting health related quality of life. Patients and their families are interested in much more than the limited follow-up currently available from most registries that document outcomes. They deserve to know information about long-term follow-up. Patients and families frequently equate the terms "long term" and "life long". While much of the information of interest will require decades of follow-up, our current follow-up infrastructure is centre-specific, frequently practitioner-specific, and not collected in any systematic fashion. Thus, it is impossible to understand and quantitate important information regarding late mortality, morbidity, complications, quality of life, and long term survival and functional status. To achieve this goal will require the definition of standardized follow-up protocols for each of the relevant diagnostic groups, irrespective of procedure performed. Guidelines for outpatient follow-up have been previously proposed by the group at The Children's Hospital of Philadelphia[119] as a template for national and international societies to discuss, modify, and use. This practice is widespread in adult cardiovascular disease, and must be adopted in paediatric and adult congenital cardiac circles. The results of follow-up investigations should be logged into the databases of the various societies to create meaningful long term follow-up in a uniform way. The definition of these follow-up protocols is urgent and should be a priority for the International Societies.

In order to accomplish this objective of meaningful long-term follow-up, many of the previous discussed areas of improvement in these databases must be operationalized. It seems plausible that the surgical database could be linked, via unique patient identifiers, to a follow-up database maintained by the physicians responsible for long-term follow-up. At the most basic level, an internet-based form could be created to allow for documentation of basic follow-up data, such as mortality, morbidity, and functional state via the classification of the New York Heart Association. This web-based form to enter the data could then be filled out every four years in all patients undergoing surgery or intervention for treatment of congenital cardiac disease. While the benefits of such a follow-up registry are self evident, challenges will exist, including practitioner "buy-in", funding of the registry, external data validation, statistical analysis with real-time feedback to practitioners, and decisions on "ownership" of the database for publication and research purposes.

Conclusions

The ultimate goal of those who established and currently use the databases of The Society of Thoracic Surgeons and The European Association for Cardio-Thoracic Surgery is the capture of all of the cardiac surgical operations for paediatric and congenital cardiac disease performed in the United States of America, Canada, and Europe. Through collaboration with other international societies, the goal becomes the eventual capture of all cardiac surgical operations for paediatric and congenital cardiac disease performed in the world. Although much has been accomplished, we can do better!!

Ultimately, we need to define the outcomes we will monitor,[79] the intervals at which we will measure and validate these outcomes, and the mechanisms by which we may merge the resultant datasets around unique patient identifiers, providing real-time feedback to practitioners on a much larger scale than currently achieved in solo practice or single centre series. Regulations designed to protect patient privacy, such as the Health Insurance Portability and Accountability Act, must be respected. We must solve the legal, technical, financial, and ethical issues using methodology that

respects patient privacy and these regulations. Methodologies must be implemented to allow uniform, protocol driven, and meaningful, long-term follow-up. This long-term follow-up is necessary to generate data to define what we do, based not only on "expert" opinion, but on validated experience. We should eventually create a multi-institutional database for congenital cardiac disease that spans geographic, subspecialty, and temporal boundaries.

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