

Procedure-Based Complications to Guide Informed Consent: Analysis of Society of Thoracic Surgeons-Congenital Heart Surgery Database

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Background. Informed consent refers to the process by which physicians and patients engage in a dialogue to explain and comprehend the nature, alternatives, and risks of a procedure or course of therapy. The goal of this study is to better "inform the process of informed consent" by offering empirically derived procedural complication lists that provide objective contemporary data that surgeons may share with patients and families.

Methods. The Society of Thoracic Surgeons Congenital Heart Surgery Database was queried for complications for 12 congenital heart operations (2010 to 2011) performed across all Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) risk categories.

Results. The 12 index procedures reviewed for rates of complications were repair of atrial septal defect (ASD), ventricular septal defect (VSD), atrioventricular septal defect (AVSD), tetralogy of Fallot (TOF), coarctation, and truncus arteriosus, as well as arterial switch operation (ASO), ASO-VSD, BiGlenn, Fontan, Norwood procedure, and systemic to pulmonary artery (S-P) shunt.

Arrhythmia was the most frequent complication for VSD (5.8%), TOF (8.9%), and AVSD (14.7%) repairs. There was a high rate of sternum left open (planned, unplanned) for ASO (26%, 7%), ASO-VSD (29%, 10%), truncus repair (41%, 11%), and Norwood (63%, 7%). The most frequent complications for other procedures include ASD (unplanned readmission, 1.9%), BiGlenn (chylothorax, 7%), Fontan (pleural effusion, 16%), S-P shunt (reintubation, 10.6%), and coarctation (reintubation, 5.2%).

Conclusions. The informed consent process for congenital heart surgery may be served by accurate contemporary data on occurrence of complications. While a threshold rate of occurrence of individual complications may guide the physician, rare but important debilitating complications should also be discussed irrespective of frequency. We propose to better inform the process of informed consent by providing objective complications data.

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Informed consent refers to a process by which physicians and patients engage in a dialogue to explain and comprehend the nature, alternatives, and risks of a procedure or course of therapy. In particular, most patients want to learn about the disease entity, its natural history, proposed operation, experience of the surgeon and team, reasonable alternatives, and the risks, including complications and mortality. The legal and moral tenets hold that the patient is responsible for her own autonomy and is free to "make medical decisions that reflect her beliefs and healthcare needs" [1]. It is assumed that this dialogue

considers cultural diversity, language barriers, psychological temperaments, socioeconomic conditions, and patient autonomy [2, 3].

Informed consent as a process was first introduced in the case of *Salgo v. Leland Stanford Jr. University Board of Trustees* [4]. In support of the litigants who claimed that physicians were not adequately performing their duty of responsible and adequate behaviors in their interactions with patients, the court ruled that "a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment" [4]. Subsequent court rulings have refined and clarified the legal concept of informed consent by broadening the scope from professional to patient-oriented standards [2] in order to further emphasize the tenets of autonomy, non-maleficence, beneficence, and justice.

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Abbreviations and Acronyms

ASD	= atrial septal defect
ASO	= arterial switch operation
AVC	= atrioventricular canal
AVSD	= atrioventricular septal defect
BBDCPA	= bilateral bidirectional cavopulmonary anastomosis or bilateral bidirectional Glenn
BDCPA	= bidirectional cavopulmonary anastomosis or bidirectional Glenn
CAVSD	= complete atrioventricular septal defect
CPS	= cardiopulmonary support
ECMO	= extracorporeal membrane oxygenation
IABP	= intraaortic balloon pump
MBTS	= modified Blalock Taussig shunt
MI	= myocardial infarction
MODS	= multi-organ dysfunction syndrome
MSOF	= multi-system organ failure
PA	= pulmonary artery
RV	= right ventricle
S-P	= systemic to pulmonary artery
STAT	= Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery risk categories
STS-CHSDB	= Society of Thoracic Surgeons Congenital Heart Surgery Database
TCP	= total cavopulmonary connection
TOF	= tetralogy of Fallot
VAD	= ventricular assist device
VSD	= ventricular septal defect

The practice of informed consent is far from standardized [1]. The discussion between patients or parents and physicians largely depends on the informing physician's knowledge of potential complications and interactive skills. These skills have been developed in the course of medical education and instantiated by role models who have taken the time to instill compassion, competence, and duty. In some instances, the informed consent process has been influenced by principles that apply to controlled, randomized, prospective clinical studies that demand certain identifiable consent processes, usually documented with comprehensive pre-printed forms that have been vetted by Institutional Review Boards [2]. The actual physician-patient interaction has not been emphasized, allowing the process to continue under the amorphous scope of "the art of medicine." Several authors [5, 6] have undertaken questionnaire studies that have chronicled physician opinion and offered suggestions, based in part on the occurrence of complications, which may guide the interaction between physician and patient. There remain significant uncertainties as to what complications should be mentioned in the informed consent process. Analysis of data in the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSDB) [7] provides important information concerning occurrence rates of a group of 6

major complications that are generally but not always specifically discussed with patients and families. How and why physicians choose from the myriad of recognized complications in order to properly perform informed consent is unknown. The informed consent process affords an opportunity to establish a personal relationship with the patient and to review the treatment plan, reveal reasonable expectations, instill confidence, project hope, and assure that complications, if they occur, will be treated in a compassionate and expeditious manner [8]. It is the "reasonable expectations" portion of this process that we address by collating objective data to inform the informed consent process for congenital heart operations.

The purpose of this study is to query the STS-CHSDB for the rates of occurrence of complications for 12 common operations, to review the literature, and to opine on the nature and process of informed consent as it applies to congenital heart surgeons.

Material and Methods

The STS-CHSDB was queried for complications (Table 1) for 12 congenital heart operations performed across all Society of Thoracic Surgeons-European Association of Cardio-Thoracic Surgery Congenital Heart Surgery (STAT) risk categories [9]. Table 2 lists these 12 operations and the STS-CHSDB procedures included in each group. All patients undergoing operations in one of the 12 procedural groups during 2010 and 2011 were eligible for inclusion in the analysis. Patients with missing data on hospital discharge status or complications were excluded from analysis, as were centers with greater than 15% missing data for complications. Standard STS-CHSDB definitions (STS-CHSDB Version 3.0) are used for the individual complications coded in the STS-CHSDB. In this study, analysis of the rates of the 6 major complications that contribute to the STS Morbidity Score [7] is likewise based on STS-CHSDB Version 3.0 codes. Summary statistics were expressed as counts and percentage frequency of occurrence for the indicated procedures.

Results

Tables 3 to 14 list complications that occurred in greater than 0.5% of patients undergoing these 12 types of operations. Arrhythmia was the most frequent complication for ventricular septal defects (VSD; 6%), tetralogy of Fallot (9%), and atrioventricular septal defect (15%) repairs. There was a high rate of sternum left open (planned, unplanned) for arterial switch operation (ASO; 26%, 7%), ASO-VSD (29%, 10%), truncus repair (41%, 11%), and Norwood (63%, 7%). The most frequent complications for other procedures include the following: atrial septal defect (unplanned readmission, 2%), BiGlenn (chylothorax, 7%), Fontan (pleural effusion, 16%), systemic to pulmonary artery/modified Blalock Taussig shunt (reintubation, 11%), and coarctation (reintubation, 5%). Figure 1 displays the frequency of the 6 major complications previously defined [7].

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