Published in final edited form as:

Pediatr Cardiol. 2008 March ; 29(2): 258–265. doi:10.1007/s00246-007-9110-2.

Application of a Complication Screening Method to Congenital Heart Surgery Admissions A Preliminary Report

Oscar J. Benavidez^a, Kimberlee Gauvreau^a, Emile Bacha^b, Pedro Del Nido^b, and Kathy J. Jenkins^a

^aDepartment of Cardiology, Children's Hospital Boston, 300 Longwood Avenue, Boston, MA 02115, USA

^bDepartment of Cardiac Surgery, Children's Hospital Boston, 300 Longwood Avenue, Boston, MA 02115, USA

Abstract

There have been comprehensive screening methods developed to identify unwanted inpatient events. A comprehensive assessment of complication diagnoses during congenital heart surgery admissions has not been performed. We examined the frequency of complications identified by a complication screening method and their relationship to patient characteristics among congenital heart surgery admissions. Data were obtained from the Healthcare Cost and Utilization Project Kids' Inpatient Database 2000. Among congenital heart surgery admissions, age ≥ 20 years, we identified *International Classification of Disease, 9th Revision, Clinical Modification* (ICD-9-CM) codes indicating complication. Complication diagnoses were categorized as related to drug/biologic, procedures, devices, implants and grafts, and radiation. We used the Risk Adjustment for Congenital Heart Surgery risk categories (1–6) to examine the association between case complexity and complications. Multivariate analyses estimated the odds for a complication diagnosis by patient characteristics, including age, prematurity, chromosomal anomalies, noncardiac structural anomalies, and surgical risk category.

Among 12,717 cases, 4014 (32%) had at least 1 complication diagnosis code. Procedure-related complication diagnoses represented 75% of complication diagnoses; device, implant, or graft represented 21%; drug/biologic represented 4% and radiation represented 0%. Multivariate analyses demonstrated that higher surgical case complexity and older age had a greater risk for a complication diagnosis: Risk Category 2, odds ratio (OR) 1.8; 3 OR 2.9; 4 OR 2.9; 5 OR 5.0; 6 OR 4.1, relative to category 1, all $p < 0.01$; age ≥ 12 years, OR 1.3, $p < 0.001$; < 1 year OR 1.1, $p = 0.31$. Premature cases had decreased odds OR 0.4, $p < 0.001$. This complication screening method indicates that unwanted patient events occur frequently during congenital heart surgery admissions. Children undergoing complex congenital heart surgery are at greatest risk for these unwanted events. Further study of these events is needed to determine their preventability and severity.

Keywords

Outcomes; Surgery complications; CHD miscellaneous

Since the Institutes of Medicine reported that patient safety events are frequent and are associated with death, there has been an increased effort to identify these unwanted patient events [1, 6, 16, 19, 20, 24]. At present, there is no completely accurate method of capturing all patient safety events in all situations. However, there have been a number of methods developed to identify patient safety events using various methods. One such method has utilized inpatient hospital administrative data, given its ubiquity among hospitals, such as the Patient Safety Indicators (PSI) developed by the Agency of Healthcare Research and Quality (AHRQ) [20, 21]. The AHRQ has also recently published a more comprehensive method of identifying patient safety events [16].

Complex pediatric patients or pediatric patients who rely on medical technologies are at increased risk for complication [29]. Admissions for congenital heart surgery regularly involve physiologically complex patients and the use of complex surgical procedures and interventions. Thus, this patient group, being both pediatric and highly complex, might be at an exceptional risk for complications.

There exist previous studies within pediatric cardiology examining complications during congenital heart surgery admissions; however, most have only examined selected patient events [4, 7, 17, 23]. There has been no examination of the findings of a comprehensive complication screening method when applied to a population-based sample of congenital heart surgery admissions.

This report utilizes a nationally representative source of pediatric data and takes advantage of a newly validated screening method for identifying complications published by the AHRQ [16]. Our study objectives are to describe the findings of this complication identification method as applied to congenital heart surgery admissions and to examine the relationship of a having a complication diagnosis to patient characteristics.

Methods

The study methods were reviewed and approved by the Institutional Review Board at Children's Hospital Boston. Given the de-identified nature of the administrative database, this project did not fit the regulatory definition of human subject research. Our institution, however, still tracks these studies by assigning a study protocol number.

Data Source

Data were obtained from the Healthcare Cost and Utilization Project Kids' Inpatient Database 2000. The Kids' Inpatient Database was designed by the AHRQ specifically to examine issues pertinent to health care delivery in children and consists of a stratified random sample of 2,516,833 discharges from 2784 institutions in 27 states¹ from the year 2000. Pediatric hospitals, academic medical centers, and specialty hospitals are included. Standard demographic and administrative data, including age, gender, race, admission type,

insurance type, median income of a patient's zip code, discharge status, and up to 15 discharge diagnostic codes and 15 procedure codes based on the *International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM)* are included.

Congenital Heart Surgery Case Selection

We selected cases 20 years of age with ICD-9-CM codes indicating surgical repair of a congenital heart defect [8]. To exclude transcatheter interventions, we eliminated atrial septal defect closure, ventricular septal defect closure, patent ductus arteriosus closure, atrial septectomy, and vessel repair or occlusion with concomitant atheterization codes and no code for cardiopulmonary bypass [9, 10].

Identification of ICD-9-CM Codes Indicating Complication

We utilized a validated method for complication screening via ICD-9-CM codes recently published by the AHRQ [16]. We chose this method because of its comprehensive panel of complication diagnoses, its use of ICD-9-CM codes to identify complication, and its previous validation and application within a pediatric discharge database [18]. This method of complication surveillance defines these unwanted events as “untoward harm associated with a therapeutic or diagnostic healthcare intervention” [16]. Designation of an event as a “complication” does not signify that the event was necessarily preventable or due to substandard care; that is, although some of these events might represent preventable or modifiable complications, others might be an unavoidable part of the patient's disease process. These events might occur at any point during the patient's admission (during anesthesia, catheterization, patient transport, surgery, intensive care unit care, inpatient ward).

This method classifies complications into four broad categories: (1) drug/biologic; (2) procedures; (3) devices, implants, and grafts; and (4) radiation. These categories are subdivided into 40 subcategories that indicate the cause of the complication. The list of ICD-9-CM codes used to define complications has been previously published by the AHRQ [16].

This method was created by a multidisciplinary group, including physicians, nurses, statisticians, a medical technologist, and epidemiologists, that identified ICD-9-CM codes indicative of complications and then validated their choices using a detailed medical record review. Using the chart review by an experienced research nurse and a two physician review as the standard for the identification of a complication, this method had a sensitivity of 60% and specificity of 97% to distinguish among cases with and without a complication diagnosis [16].

A discharge was considered to have a complication diagnosis if any of the diagnosis fields contained at least one of the ICD-9-CM codes listed in the surveillance criteria for complication. A given patient discharge could have more than one complication.

¹Arizona, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Missouri, North Carolina, New Jersey, New York, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, and West Virginia.

Risk Adjustment for Congenital Heart Surgery and Complication

The Risk Adjustment for Congenital Heart Surgery (RACHS-1) method was developed and validated to adjust for differences in case mix complexity when examining in-hospital death rates after congenital heart surgery [9, 10]. Cases with a higher surgical risk category have greater odds for mortality. The ability of RACHS-1 to predict cases at greater risk for mortality has been previously described [9]. The association of surgical risk category, as an indicator of surgical case complexity, and complication has not been explored.

Methods for RACHS-1 risk categorization have been previously described [10]. To perform RACHS-1 risk categorization, cases were assigned to one of six risk categories based on the presence or absence of specific diagnosis and procedure codes, where category 1 is the least complex (e.g., atrial septal defect repair) and category 6 is the most complex (e.g., Norwood operation for hypoplastic left heart syndrome). Cases with a combination of cardiac surgical procedures were placed in the category corresponding to the single highest risk procedure. Cases that are ineligible for RACHS-1 categorization are cases $\geq$ 18 years of age (adults), cardiac transplantation, patent ductus arteriosus ligation in premature infants, and patent ductus arteriosus ligation in infants less than 30 days. Cases that cannot be categorized are, generally, cases where the procedure codes are vague and the specific cardiac surgery performed is not known for certain. These methods have been previously discussed [9, 10]. Examples of surgical procedures within each risk category are illustrated in the Appendix.

Data Analysis

Complication frequency was reported as the number of complications per 1000 cases. A patient discharge might have had more than one complication. Complication diagnoses were stratified according to the four complication categories. The univariate relationships between patient characteristics (gender, age, prematurity, presence of a major noncardiac structural anomaly, presence of a major chromosomal abnormality, and surgical risk category) and the proportion of admissions with a complication were explored using the chi-square test. Multivariate analyses, using generalized estimating equations (GEE) models with exchangeable correlation and empirical (robust) variance estimation incorporating patient variables and surgical risk category, estimated the odds ratio (OR) for a reported complication diagnosis. GEE models account for the intrainstitutional correlation among cases from the same hospital, and in this analysis, it was assumed that the correlation was constant for any two cases at the same institution. The outcome variable in GEE models was presence of any complication yes or no, a dichotomous variable. Admissions were not counted more than once. The statistical package SAS Version 9.1 (SAS Institute Inc., Cary, NC) was used.

Results

Table 1 illustrates the characteristics of the patient sample. There were a total of 12,717 congenital heart surgery admissions identified, 46% were female and greater than one-half (55%) were less than 1 year, followed by cases between 1 and 11 years (34%) and those $\geq$ 12 years (11%). Premature cases represented 10%, cases with a major noncardiac structural

anomaly represented 4%, and cases with a chromosomal abnormality were 11% of the study sample. The distribution of cases among the six risk categories and those cases that were ineligible for risk categorization or could not be categorized by the RACHS-1 method are tabulated in Table 1.

Among the 12,717 cardiac surgical admissions identified, 4014 (32%) had at least 1 complication diagnosis code; there were a total of 6650 diagnosis codes indicating a complication (523 complications per 1000 cases). Procedure- related complication diagnosis codes were the largest category and represented 75% of all reported complication diagnoses, occurring with a frequency of 392 per 1000 cases. Device-, implant-, or graft-related complications were the second most common and represented 21% of reported complication diagnosis codes and occurred with a frequency of 111 per 1000 cases. Drug/biologic-related complications were 4% of reported complication codes and occurred with a frequency of 20 per 1000 cases. There were no reported radiation complication codes. The three most frequently reported complication diagnosis codes are ICD-9-CM code 997.1, Procedural complication–heart (cardiac arrest, cardio-respiratory failure during or resulting from a procedure), ICD-9-CM code 997.3, Procedural complication–respiratory (pneumonia, aspiration), and ICD-9-CM code 998.11, Hemorrhage complicating a procedure. Together these three complication codes comprise 37% of all complication diagnosis codes identified.

Patient Characteristics and Complication Diagnosis Codes

Tables 2 and 3 illustrate the univariate analyses of patient characteristics and their association with a complication diagnosis. Gender, age, prematurity, and chromosomal abnormalities were associated with an increased rate of complication diagnoses. Males had a slightly greater rate of reported complication diagnosis codes than females (33% vs 30% of cases, $p < 0.001$). Cases with a major chromosomal abnormality were also associated with a greater proportion of complication codes than those without such a diagnosis (33.8% vs 31.3%, $p = 0.05$). Premature cases were associated with fewer reported complication codes (19.1% vs 32.9%, $p < 0.001$). Major noncardiac structural anomalies were not associated with increased rate of complication diagnoses.

Surgical Case Complexity and Complication Diagnosis

Among the 12,717 congenital heart surgery cases in the Kids' Inpatient Database for the year 2000, 1336 were ineligible for RACHS-1 categorization and 1349 congenital heart surgery cases could not be categorized to a RACHS-1 risk category due to vague or unclear coding of the surgical procedure. The relationship between reported complication diagnosis codes and surgical risk category is shown in Table 3. Figure 1 plots the percentage of admissions with complication diagnosis codes by surgical risk category with 95% confidence intervals. In general, the higher the risk category, the higher the rates of reported complication diagnosis code (category 1, 18.1%; category 2, 27.8%; category 3, 38.9%; category 4, 39.1%; category 5, 55.6%; category 6, 47.3%). The percentages for risk categories 3 and 4 were very similar. There were only nine total cases in risk category 5; this small number of cases and the relatively large fraction of complications reported resulted in a wide

confidence interval. Only cases that could be assigned to a surgical risk category were included in this analysis.

Patient Characteristics, Surgical Complexity, and Complications

Our multivariate analysis incorporating patient characteristics and surgical risk category demonstrated that age and surgical risk category were independently associated with an increased risk for a complication diagnosis (Table 4). Age category greater than 12 years was associated with the greatest risk for complication diagnostic code; 12 years OR 1.3, $p = 0.001$, <1 year OR 1.1, $p = 0.31$ vs 1–11 years. The surgical risk category remained significantly associated with complication, with higher-risk cases being associated with greater risk for complication relative to category 1 (category 2 OR 1.8, $p < 0.001$; category 3 OR 2.9, $p < 0.001$; category 4 OR 2.9, $p < 0.001$; category 5 OR 5.0, $p = 0.006$; category 6 OR 4.1, $p < 0.001$; not categorized OR 2.9, $p < 0.001$; not eligible 2.8, $p < 0.001$). Prematurity was associated with substantially fewer reported complication codes: premature OR 0.4, $p < 0.001$.

Gender, major noncardiac structural anomalies, and major chromosomal anomalies were not independently associated with a reported complication code.

Comment

When applied to congenital heart surgical admissions, this screening method found a complication diagnosis code in nearly one-third of admissions and those admission with complex surgical procedures were more likely to screen positive for a complication diagnosis. Procedure-related complications are the most common type of complication diagnosis, followed by complications due to a device, graft, or implant. Compared to other pediatric age groups, cases greater than 12 years are more likely to have a complication diagnosis. Premature cases are less likely to have a reported complication diagnosis.

There are no comprehensive studies of adverse patient events or complications within pediatric cardiology with which to compare our results. However, studies have examined selected events during congenital heart surgery admissions and support our findings that complications occur with a relatively high frequency. A prospective study of patients admitted to a pediatric cardiac intensive care unit found that 18% of admissions experienced nonsustained ventricular tachycardia related to their medical or surgical intervention [7]. Other studies examining nosocomial infections during congenital heart surgery admissions have reported that up to 16–22% of these patients acquired at least one nosocomial infection [14, 17, 23]. The rates of other selected complications during congenital heart surgery admissions have been reported; for example, catheter-related septic emboli occurs at a rate of 0.55% [5], diaphragmatic paralysis occurs at a rate of 5.4% [12], cardiac tamponade occurs at a rate of 0.04–7% [11], and hepatic complication occurs at a rate of 9% [30]. There are also several case reports of isolated complications during congenital heart surgery admissions [2, 11, 22, 25–28, 31]. These studies use different methods of identifying these events and generally have not examined the relationship between these events and congenital heart surgical case complexity. Again, these studies do not represent a comprehensive assessment of patient complication events.

Comprehensive studies of complications and patient safety events within the general pediatric population have been performed. Meurer et al. [18] applied the above complication identification method to hospital discharge records from the State of Wisconsin Bureau of Health Information to discharges under 18 years. This study demonstrated a complication frequency of 341 per 10,000 cases among the general pediatric population. Our findings suggest that congenital heart surgery admissions might have a greater frequency of complication diagnoses than do general pediatric admissions.

Our finding that increased congenital heart surgery case complexity is associated with an increased risk for patient safety event is consistent with the pediatric patient safety literature. Slonim et al. also demonstrated that children with special needs or who are reliant on specialized technologies are at greater risk for patient safety events [29]. A study by Koezer et al. within the pediatric emergency department found that the most seriously ill pediatric patients are more likely to be subjected to patient safety events [15]. Our study also found that premature cases are associated with fewer reported complication codes compared to nonpremature cases. This interesting finding is consistent with a study by Kanter et al. [13] of neonatal care that reported that the rate of medical errors reported during premature admissions was lower than that for general pediatric and adult patients. Future work is needed to inform this consistent finding among premature patients. Our findings are also consistent with previous studies reporting discharges within an older pediatric age range have been associated with increased risk for patient safety events. This finding has been previously reported by a study by Miller et al. using AHRQ indicators [20].

The database does not allow us to answer the question of why these consistent and counterintuitive findings are present. However, one might speculate that neonatal intensive care units, being very highly specialized arenas of patient care with decades of experience with specialized neonatal care, might have resolved systems and process issues that might have previously caused complications of care. As result of this long specialized history (as opposed to general pediatric intensive care units and pediatric cardiac intensive care units), they might have developed strategies to decrease the number of complicating events in their setting and among their population.

Limitations and Strengths

Administrative data, although useful, are limited due to coding inaccuracies, coding variation, and lack of insight into timing and severity of clinical events. Another limitation of our study is the complication identification method published by the AHRQ and used in this study was meant to be a generally applicable, comprehensive panel of complications. This method was not specifically designed to identify complications during congenital heart surgery admissions. As a result, these criteria might identify some events as complications that might be unimportant in our study sample or might be part of the patient's underlying disease process. It is also possible that this method might also exclude important events. Presently, however, a complication surveillance method designed for congenital heart surgery admissions does not exist.

Our study has many strengths, including use of a nationally representative pediatric discharge database that includes discharges from pediatric and nonpediatric hospitals created specifically to examine health outcomes within pediatrics by the AHRQ, a federal agency that was given the mandate by Congress to study adverse patient events. This database also reports a mortality of 4% for congenital heart surgery, which is identical to the mortality rate reported in the Society of Thoracic Surgeons database for pediatric congenital heart surgery; this finding supports the validity of the administrative database employed in this study. We utilized a complication screening method that has been validated for use with pediatric administrative discharge databases. In addition, given that cardiac surgical care is procedure based, our finding that complications related to procedures or devices were most important is internally consistent and adds further credibility.

Conclusion

The findings of this complication screening method are consistent with the patient safety literature in identifying a high frequency of complications during congenital heart surgery admissions and that more complex admissions are more likely to have a complication. This complication screening method cannot determine the severity or preventability of the complications identified. Additional work is needed to determine the severity and potential preventability of these events and to develop a complication measure specifically for congenital heart surgery admissions.

Acknowledgments

Funding: This work was supported in part by a charitable grant from the Hill family.

This work was supported by the National Institutes of Health under award number: T32HL007572. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Appendix: Examples of Individual Procedures by Risk Category [3]

Risk Category 1:

- Atrial septal defect (ASD) surgery (including ASD secundum, sinus venosus ASD and patent foramen ovale closure)
- Aortopexy
- Patent ductus arteriosus surgery at age <30 days

Risk Category 2:

- Aortic valvotomy or valvuloplasty at age <30 days
- Subaortic stenosis resection
- Glenn shunt

Risk Category 3:

- Aortic valve replacement
- Ross procedure
- Mitral valvotomy or valvuloplasty

Risk Category 4:

- Konno procedure
- Arterial switch operation with ventricular septal defect closure
- Repair of total anomalous pulmonary veins at age <30 days

Risk Category 5:

Tricuspid valve surgery for Ebstein anomaly age 30 days
 Repair of truncus arteriosus and interrupted aortic arch

Risk Category 6:

Stage 1 repair of hypoplastic left heart syndrome
 Stage 1 repair of nonhypoplastic left heart syndrome conditions
 Damus–Kaye–Stansel procedure

References

1. Bates DW. David Westfall Bates, MD: a conversation with the editor on improving patient safety, quality of care, and outcomes by using information technology. *Proc Bayl Univ Med Center*. 2005; 18:158–164. Interview by William Clifford Roberts. [PubMed: 16200166]
2. Berger A, Wollenek G, Hermon M, Burda G. Excessive bleeding on extracorporeal membrane oxygenation after surgical repair of type I truncus arteriosus: A case report. *Artif Organs*. 1999; 23:1033–1035. [PubMed: 10564312]
3. Connor JA, Gauvreau K, Jenkins KJ. Factors associated with increased resource utilization for congenital heart disease. *Pediatrics*. 2005; 116:689–695. [PubMed: 16140709]
4. Dagan O, Cox PN, Ford-Jones L, et al. Nosocomial infection following cardiovascular surgery: comparison of two periods, 1987 vs. 1992. *Crit Care Med*. 1999; 27:104–108. [PubMed: 9934902]
5. Erez E, Sharoni E, Ovadia B, et al. Septic emboli caused by vascular catheters after surgery for congenital heart disease. *Crit Care Med*. 2000; 28:845–847. [PubMed: 10752840]
6. Gandhi TK, Seger DL, Bates DW. Identifying drug safety issues: from research to practice. *Int J Qual Health Care*. 2000; 12:69–76. [PubMed: 10733086]
7. Hoffman TM, Wernovsky G, Wieand TS, et al. The incidence of arrhythmias in a pediatric cardiac intensive care unit. *Pediatr Cardiol*. 2002; 23:598–604. [PubMed: 12530491]
8. Jenkins KJ, Gauvreau K. Center-specific differences in mortality: preliminary analyses using the Risk Adjustment in Congenital Heart Surgery (RACHS-1) method. *J Thorac Cardiovasc Surg*. 2002; 124:97–104. [PubMed: 12091814]
9. Jenkins KJ, Gauvreau K, Newburger JW, et al. Validation of relative value scale for congenital heart operations. *Ann Thorac Surg*. 1998; 66:860–869.
10. Jenkins KJ, Gauvreau K, Newburger JW, et al. Consensusbased method for risk adjustment for surgery for congenital heart disease. *J Thorac Cardiovasc Surg*. 2002; 123:110–118. comment. [PubMed: 11782764]
11. Johnston LJ, McKinley DF. Cardiac tamponade after removal of atrial intracardiac monitoring catheters in a pediatric patient: case report. *Heart Lung*. 2000; 29:256–261. [PubMed: 10900062]
12. Joho-Arreola AL, Bauersfeld U, Stauffer UG, et al. Incidence and treatment of diaphragmatic paralysis after cardiac surgery in children. *Eur J Cardiothorac Surg*. 2005; 27:53–57. [PubMed: 15621471]
13. Kanter DE, Turenne W, Slonim AD. Hospital-reported medical errors in premature neonates. *Pediatr Crit Care Med*. 2004; 5:119–123. [PubMed: 14987340]
14. Kollef MH, Sharpless L, Vlasnik J, et al. The impact of nosocomial infections on patient outcomes following cardiac surgery. *Chest*. 1997; 112:666–675. [PubMed: 9315799]
15. Kozier E, Scolnik D, Macpherson A, et al. Variables associated with medication errors in pediatric emergency medicine. *Pediatrics*. 2002; 110:737–742. [PubMed: 12359787]
16. Layde, PM.; Meurer, LN.; Guse, C., et al. Patient safety monitoring: identification of medical injuries using hospital discharge data. In: Henriksen, K.; Battles, JB.; Lewin, DL., editors. *Advances in patient safety: From research to implementation Vol 2, Concepts and methodology*. Agency for Healthcare Research and Quality; Rockville, MD: 2005. p. 119-132.
17. Levy I, Ovadia B, Erez E, et al. Nosocomial infections after cardiac surgery in infants and children: incidence and risk factors. *J Hosp Infect*. 2003; 53:111–116. [PubMed: 12586569]

18. Meurer, J.; Yang, H.; Guse, C., et al. Pediatric Academic Societies' Annual Meeting, 2004. San Francisco, CA: 2004. Medical injuries among children hospitalized in Wisconsin.
19. Michel P, Quenon JL, de Sarasqueta AM, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *Br Med J*. 2004; 328:199. [PubMed: 14739187]
20. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalizations. *Pediatrics*. 2003; 111:1358–1366. [PubMed: 12777553]
21. Miller MR, Zhan C. Pediatric patient safety in hospitals: a national picture in 2000. *Pediatrics*. 2004; 113:1741–1746. [PubMed: 15173500]
22. Mogayzel PJ Jr, Colombani PM, Crawford TO, Yang SC. Bilateral diaphragm paralysis following lung transplantation and cardiac surgery in a 17-year-old. *J Heart Lung Transplant*. 2002; 21:710–712. [PubMed: 12057707]
23. Mrowczynski W, Wojtalik M, Zawadzka D, et al. Infection risk factors in pediatric cardiac surgery. *Asian Cardiovasc Thorac Ann*. 2002; 10:329–333. [PubMed: 12538279]
24. O'Neil AC, Petersen LA, Cook EF, et al. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med*. 1993; 119:370–376. [PubMed: 8338290]
25. Parry RL, Gordon S, Sherman NJ. Pulmonary artery band migration producing endobronchial obstruction. *J Pediatr Surg*. 1997; 32:48–49. [PubMed: 9021567]
26. Rosen DA, Hawkinberry DW 2nd, Rosen KR, et al. An epidural hematoma in an adolescent patient after cardiac surgery. *Anesth Analg*. 2004; 98:966–969. [PubMed: 15041581]
27. Sharoni E, Erez E, Birk E, et al. Superior vena cava syndrome following neonatal cardiac surgery. *Pediatr Crit Care Med*. 2001; 2:40–43. [PubMed: 12797887]
28. Sivan Y, Nutman J, Zeevi B, et al. Acute hepatic failure after open-heart surgery in children. *Pediatr Cardiol*. 1987; 8:127–130. [PubMed: 3628068]
29. Slonim AD, LaFleur BJ, Ahmed W, Joseph JG. Hospitalreported medical errors in children. *Pediatrics*. 2003; 111:617–621. [PubMed: 12612245]
30. Vazquez P, Lopez-Herce J, Carrillo A, et al. Hepatic dysfunction after cardiac surgery in children. *Pediatr Crit Care Med*. 2001; 2:44–50. [PubMed: 12797888]
31. Watanabe T, Tajima K, Shimomura T, et al. Intraabdominal bleeding after repair of total anomalous pulmonary venous connection. *Thorac Cardiovasc Surg*. 1997; 45:207–209. [PubMed: 9323826]

Fig. 1. Percentage of cases with a complication by congenital heart surgical risk category

Table 1
Study sample characteristics

	No. of cases	Percent
Total	12,717	
Gender ^a		
Female	5888	46%
Male	6825	54%
Age group ^b		
< 1 year	6975	55%
1-11 years	4304	34%
12 years	1432	11%
Premature	1202	10%
Major noncardiac structural anomaly	494	4%
Major chromosomal abnormality	1427	11%
Risk category		
1	1876	15%
2	3466	27%
3	3450	27%
4	895	7%
5	9	<1%
6		336
	2% Not categorized	1349
	11% Not eligible	1336

^a Four cases missing

^b Six cases missing

Table 2
Rates of complication by patient characteristics

	No. of cases	Proportion with complication code (%)	<i>p</i> -Value
Total	12,717	31.6	---
Gender			
Male	6825	33.0	<0.001
Female	5888	30.0	
Age group			
<1 year	6975	32.1	<0.001
1-11 years	4304	29.3	
12 years	1432	35.7	
Premature			
Yes	1202	19.1	<0.001
No	11,515	32.9	
Major noncardiac structural anomaly			NS
Yes	494	34.8	
No	12,223	31.4	
Major chromosomal abnormality			
Yes	1427	33.8	0.050
No	11,290	31.3	

Table 3
Percentage of cases with a complication by congenital heart surgical risk category

Risk category	Percent	95% Confidence interval
1	18.1	(16.4, 19.9)
2	27.8	(26.3, 29.3)
3	38.9	(37.2, 40.5)
4	39.1	(35.9, 42.4)
5	55.6	(21.2, 86.3)
6	47.3	(41.9, 52.8)

Table 4
Multivariate analysis

	OR	95% Confidence interval	p-Value
Gender			
Male	1.1	[1.0, 1.2]	0.09
Age group			
<1 year	1.1	[0.9, 1.2]	0.31
1-11 years	1.0	-	-
12 years	1.3	[1.1, 1.4]	0.001
Premature	0.4	[0.3, 0.6]	<0.001
Major noncardiac structural anomaly	1.2	[0.9, 1.5]	0.14
Major chromosomal abnormality	1.0	[0.9, 1.2]	0.97
Risk category			
1	1.0	-	
2	1.8	[1.5, 2.1]	<0.001
3	2.9	[2.4, 3.6]	<0.001
4	2.9	[2.2, 3.9]	<0.001
5	5.0	[1.6, 15.8]	0.006
6	4.1	[3.0, 5.8]	<0.001
Not categorized	2.9	[2.3, 3.5]	<0.001
Not eligible	2.8	[2.1, 3.7]	<0.001