Variability in data: The Society of Thoracic Surgeons National Adult Cardiac Surgery Database

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Objective: Since 1989, data have been reported to the Society of Thoracic Surgeons National Adult Cardiac Surgery Database for quality improvement. This information is also data mined for national quality indicators, policy initiatives, and research. Such use has important limitations, because data elements cannot be verified for accuracy. We determined variability of disease etiology and operative data database elements when abstracted by untrained physician abstractors.

Methods: We selected 30 patients who underwent cardiovascular surgery from January to December 2005 (10 each of coronary artery bypass grafting, mitral valve repairs, and aortic valve and associated aortic procedures). Four abstractors (2 cardiothoracic residents and 2 fellows) abstracted 28 variables. Results were compared with abstraction performed by a professional abstractor.

Results: Median percentage agreement among all cases was 89% (range, 42%–100%). Agreements were 94% (28%–100%) for mitral valve, 84% (48%–100%) for aortic valve, and 93% (35%–100%) for coronary artery bypass grafting. Among the aortic valve group, etiology of aortic valve disease had poor agreement (68%) because of cases in which multiple definitions could apply. Degree of valvular regurgitation also had poor agreement (median, 67%; range, 28%–95%). Number of internal thoracic artery grafts and absence of significant valvular disease were reported consistently. Agreements between types of aortic valve procedure and between methods of mitral valve repair (65% and 83%, respectively) were less than expected.

Conclusions: We found variable agreement among untrained data abstractors. This has important implications regarding interpretation of database studies with de-identified data. Without good quality control and consistent standardized definitions, aggregate data in clinical databases may be suspect. (*J Thorac Cardiovasc Surg* 2010;140:267-73)

The Society of Thoracic Surgeons (STS) National Adult Cardiac Surgery Database (NCD) is a North American cardiac surgical database designed to support quality improvement (<http://www.sts.org>). Since its development in 1989, there has been an increasing focus on obtaining and maintaining a high quality of data through on-site data managers, point-of-entry data controls, and annual national database meetings.¹⁻³ The measures of data quality used by the STS NCD, however, are generally limited to controlling for missing data, inconsistent data, and outliers or extreme

data values. Only recently has there been implementation of site checking with repeated abstraction of data by data quality personnel,⁴ and results of these repeated abstractions have not yet been reported by the STS NCD. Our objective was to examine the amount of variability present in variables of diagnosis and operation type during data collection by untrained abstractors for the STS NCD at a single institution.

MATERIALS AND METHODS

After institutional review board approval and waiver of the need for individual patient consent, we identified patients who had undergone isolated coronary artery bypass grafting (CABG), mitral valve repair, and aortic valve or aortic procedures between January 1 and December 31, 2005. From these, a convenience sample of 10 cases was selected from each operative type, representing a variety of diagnoses and operative procedures. The year 2005 was selected because all medical records were available electronically, and the residents and fellows were not present at our clinic for any of these cases, removing the impact of recall bias. Four abstractors were identified, including 2 cardiothoracic surgical residents and 2 cardiovascular surgical fellows who were all familiar with the electronic medical record and had previous research abstraction experience. These resident and fellow abstractors were instructed in collecting variables for the STS database, including all relevant definitions provided by the STS, and were blinded to the results of the professional abstractors and those of one another. Each of the resident and fellow abstractors each reviewed all 30 patient records. These results were compared with the abstraction performed by a professional abstractor.

Data elements were identified from STS version 2.52 and included definitions of diagnoses and operation types. The variables chosen are listed in

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Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
NCD	= National Adult Cardiac Surgery Database
STS	= Society of Thoracic Surgeons

Table 1. The variable describing valvular etiology, selected from STS version 2.35, has been removed in later versions of the core fields of the STS database but is still captured at Mayo Clinic. Resident and fellow abstractors, as well as the professional abstractor, used all information available in the electronic medical record, including operative reports, echocardiograms, cardiac catheterization reports, pathologic examinations, and any clinical notes. For internal quality control, residents and fellows also abstracted the surgeon and assistant on record for the procedure. This had 100% agreement in all cases, and these variables were not considered in further analyses.

Operations (n = 30) were analyzed as a group as well as by separate procedure (mitral valve repair, CABG, and aortic valve or aortic procedures). Overall percentage agreements between physician abstractors and professional abstractor were calculated with the data abstractor considered as the criterion standard. In addition, Fleiss κ values were calculated for all variables to account both for multiple abstractors and for multiple categories of possible rater responses for most variables.⁵ Fleiss κ represents the degree of agreement in classification beyond that which would be expected by chance and is scored between 0 and 1. Stats Direct statistical software (version 2.6.2; StatsDirect Ltd, Altrincham, UK) was used for all calculations.

RESULTS

The median percentage agreement among all cases was 89% (range, 42%–100%; **Figure 1**), and the κ values are listed in **Table 2**. The best agreement was for variables that were not present in any patients, such as pulmonary valve stenosis and annular enlargement procedure. These both had 100% agreement, and κ values cannot be calculated for conditions that are not present. The poorest agreement occurred in the assessment of tricuspid valve regurgitation (VDInsufT), but this was most often only 1 category of difference: none versus trivial, trivial versus mild, mild versus moderate, or moderate versus severe ($\kappa = 0.206$). This was due both to multiple sources of data for tricuspid regurgitation (transthoracic echocardiograms, transesophageal echocardiograms, and occasional cardiac catheterization or magnetic resonance imaging) and to how reports of regurgitation that included 2 categories were handled (eg, moderate to severe regurgitation). The mitral valve repair group had a median percentage agreement of 94% (28%–100%) for all fields (**Figure 2**). The degree of mitral valve regurgitation (VDInsufM), status of the operation (Status), and number of diseased vessels (NumDisV) were collected consistently (median percentage agreements >95%). When looking at the type of mitral valve repair, however, there was only 83% agreement. Differences in interpretation of mitral valve repair type were most frequently due to confusion about the definition of mitral valve recon-

TABLE 1. Data elements from the Society of Thoracic Surgeons National Adult Cardiac Database assessed for variability

Variable name	Variable meaning
Surgeon	Primary surgeon
Assistant	Primary assistant
VDStenA	Aortic valve stenosis
VDStenM	Mitral valve stenosis
VDStenT	Tricuspid valve stenosis
VDStenP	Pulmonary valve stenosis
VDInsufA	Aortic valve insufficiency
VDInsufM	Mitral valve insufficiency
VDInsufT	Tricuspid valve insufficiency
VDInsufP	Pulmonary valve insufficiency
VDEtiolA	Aortic valve etiology
VDEtiolM	Mitral valve etiology
VDEtiolT	Tricuspid valve etiology
VDEtiolP	Pulmonary valve etiology
ReopRsn	Reason for reoperation
Status	Urgency of operation
AnlrEnl	Annular enlargement procedure
OpAortic	Aortic valve procedure type
OpMitral	Mitral valve procedure type
ONCAoAn	Aortic aneurysm
ONCAsc	Ascending aortic aneurysm
ONCArch	Aortic arch aneurysm
NumDisV	No. of diseased vessels
LMainDis	Left main coronary artery disease
IMAArtUs	Internal thoracic arteries used
RadArtUs	Radial arteries used
DistArt	No. of distal anastomoses with arterial conduits
DistVein	No. of distal anastomoses with venous conduits

struction with or without annuloplasty. Although the STS definition mentions that annuloplasty requires placement of an annuloplasty ring, there were cases in which a suture annuloplasty was performed, such as a Kay stitch, and these were coded as annuloplasty by some of the untrained abstractors.

In the aortic valve or aortic procedure group, the percentage agreement ranged between 48% and 100%, with a median value of 84% for all fields (**Figure 3**). Variables of aortic stenosis (VDStenA) and replacement of the aortic arch (ONCArch) had median percentage agreements of 93% and 93%, respectively. Among patients in the aortic valve or aortic procedure group, the lowest agreement was seen in the degree of mitral valve regurgitation (VDInsufM), which was most commonly misclassified by only 1 category. If VDInsufM was dichotomized to none, trivial, or mild versus moderate or severe, the κ value was 0.970, but if VDInsufM was dichotomized to none or trivial versus mild, moderate, or severe, the κ value decreased to 0.756. It was notable that the type of aortic valve procedure (OpAortic) had a median agreement of only 65%. This was primarily due to variability regarding the coding of root reconstruction with valve sparing versus resuspension aortic valve with

FIGURE 1. Percentage agreement for all definitions (given in Table 1) in all operations.

replacement of ascending aorta versus resuspension aortic valve without replacement of ascending aorta.

Data for patients undergoing CABG had a median agreement of 93% (range, 35%–100%) for all fields (Figure 4).

TABLE 2. Fleiss κ values for all patients with records abstracted

Variable	Fleiss κ
Aortic valve stenosis	0.62 $\pm$ 0.06
Mitral valve stenosis	0.13 $\pm$ 0.06
Tricuspid valve stenosis	–0.02 $\pm$ 0.06
Pulmonary valve stenosis	NA
Aortic valve insufficiency	0.50 $\pm$ 0.03
Mitral valve insufficiency	0.56 $\pm$ 0.04
Tricuspid valve insufficiency	0.21 $\pm$ 0.04
Pulmonary valve insufficiency	0.04 $\pm$ 0.04
Aortic valve etiology	0.66 $\pm$ 0.04
Mitral valve etiology	0.66 $\pm$ 0.03
Tricuspid valve etiology	–0.02 $\pm$ 0.06
Pulmonary valve etiology	NA
Reason for reoperation	0.50 $\pm$ 0.03
Urgency of operation	0.57 $\pm$ 0.04
Annular enlargement procedure	NA
Aortic valve procedure type	0.49 $\pm$ 0.03
Mitral valve procedure type	0.35 $\pm$ 0.09
Aortic aneurysm	0.59 $\pm$ 0.1
Ascending aortic aneurysm	0.36 $\pm$ 0.1
Aortic arch aneurysm	0.58 $\pm$ 0.1
No. of diseased vessels	0.69 $\pm$ 0.06
Left main coronary artery disease	0.78 $\pm$ 0.1
Internal thoracic arteries used	1.00 $\pm$ 0.1
Radial arteries used	0.73 $\pm$ 0.1
No. of distal anastomoses with arterial conduits	0.79 $\pm$ 0.03
No. of distal anastomoses with venous conduits	0.83 $\pm$ 0.06

Fleiss κ values (listed as $\kappa \pm$ SE) are influenced by number of categories or ratings possible for any variable. In addition, κ values are less reliable in cases of rare events. Fleiss κ values cannot be calculated if there are no events in the variable of interest. NA, Not applicable.

Importantly, internal thoracic artery usage (IMAArtUs) had a 100% agreement, and numbers of distal vessels (DistArt and DistVein) had agreements greater than 90%. Left main disease had an agreement of 88% and number of diseased vessels had an agreement of 78%, however, both of which are less than would be expected. The urgency of operation had only a 68% agreement, despite lengthy definitions provided by STS.

DISCUSSION

In our study, variables abstracted for the STS NCD had a median percentage agreement of 89%, but there was a wide range between 42% and 100%. These results demonstrate the potential variability when abstracting data for institutional registries such as the STS NCD. There are 3 potential problems with the abstraction of clinical data: the quality of the available source material, the definitions and timing of variables captured, and the interpretation of the source materials and definitions by an abstractor.

The quality of the available source material is an important issue. At many institutions, there may be inconsistent availability and completeness of echocardiographic and angiographic reports, operative reports, pathology reports, and clinical records. At Mayo Clinic, there is a single universal chart for the patient. In other practices, however, a given patient may have data scattered among many charts located in different physician offices, divisions, or departments, and the most important current data may not be available to the abstractor.

In addition, clinical data may change during the duration of a hospital admission. In the materials provided by STS, there are no guidelines in the definitions or in the frequently asked questions section regarding how source materials should be prioritized and the timing of when data should be extracted

FIGURE 2. Percentage agreement for all definitions (given in Table 1) collected for patients who underwent mitral valve repair procedures. κ values and SEs are listed for each variable. NA, Not applicable.

in the patient's medical history.¹⁻³ For example, a patient might be admitted with severe congestive heart failure and severe mitral and tricuspid valve regurgitation, but adequate diuresis might subsequently reduce tricuspid regurgitation to the category of mild. If such a patient undergoes mitral valve and tricuspid valve repair, there are no guidelines with regard to the appropriate time to abstract data on the degree of tricuspid valve regurgitation. Individual centers may have internal consistency in these matters, but without

clarification from the STS, data may not be comparable among centers in research studies.

The STS has a database committee that works to develop precise and clear definitions for the STS NCD. In addition, the STS provides a frequently asked questions file, and there is a contact at the central office to ask questions. As our study has demonstrated, however, there remains some confusion regarding definitions. Some confusion, for example about the fields regarding valvular etiology or reason for

FIGURE 3. Percentage agreement for all definitions (given in Table 1) collected for patients who underwent aortic valve or aortic procedures. κ values and SEs are listed for each variable. NA, Not applicable.

FIGURE 4. Percentage agreement for all definitions (given in Table 1) collected for patients who underwent coronary artery bypass grafting procedures. κ values and SEs are listed for each variable. NA, Not applicable.

reoperation, is due to the exclusionary nature of the question, in which only a single response may be given even though many (such as rheumatic, calcific, and congenital for a stenotic bicuspid aortic valve) may be appropriate. Other disagreements regarding definitions are due to the complex nature of cardiovascular surgery, such as aortic valve and root procedures. There would be debate among surgeons themselves as to whether the ascending aorta is replaced if a surgeon performs an aortic root replacement. And how are patients categorized who undergo replacement of the ascending aorta and noncoronary sinus? Definitions may be able to be further clarified in the STS NCD to ensure consistent data collection, and the variability present in data elements should be assessed and made available.

The interpretation of source materials and definitions by abstractors is a critical step in the acquisition of accurate data. At Mayo Clinic, we have a trained data manager and 4 data abstractors who work full-time on collection of data and have accumulated decades of experience. They have created additional “data rules” for themselves to deal with many of these issues of data interpretation. They interact with each other when needed and can also consult the supervisor. The chair of the division of cardiovascular surgery also meets with the supervisor regularly to resolve issues of data interpretation. Our study was not designed to examine internal consistency of our data abstractors; we believe that we already achieve this through frequent education and the development of in-house “data rules.” Our study does demonstrate, however, that with available definitions the use of untrained abstractors, even those with experience in cardiovascular surgery, may lead to considerable misclas-

sification. This underlines not only the importance of providing not only clear and consistent definitions but also the need for formal abstractor training and certification, and perhaps recertification.

Recently Clarke and associates⁴ evaluated quality of data contained in the STS congenital cardiac surgery database. Five randomly selected centers with a minimum of 30 congenital operations in 2006 were selected for repeated abstraction by independent abstractors, including a database manager and cardiac surgeon. Administrative data had a percentage agreement ranging between 87% and 97%, and agreement for intraoperative data ranged between 94% and 100%. Categorization of the primary procedure had an agreement of only 72%, however, and that of the primary diagnosis had an agreement of 74%. It is probable that diagnosis and procedure identification are much more difficult in congenital cardiac surgery than in adult acquired cardiac surgery. Our study, however, did show an overall agreement of 89% for adult cardiac surgery diagnoses and operative procedure types, which is comparable to the results from the congenital STS database.

One may question the necessity of obtaining such a high degree of accuracy in a voluntary registry database. A recent study deliberately miscoded a database with missing data, changes in vital status, and misclassification of operative procedures; the investigators found that even small amounts of data error (1%–5%) could lead to misleading analyses.⁶ In that study of congenital cardiac surgical patients, misclassification of low-risk procedures as high-risk procedures led to a lower calculated mortality, whereas high-risk operations misclassified as low-risk operations led to a higher calculated

mortality. If these results were to be translated into large databases, there would potentially be a great amount of error, which could be reflected in both the assessment of quality of an institution and the ability to conduct research.

Another study of isolated CABG procedures examined the rates of error within a single institution's STS database, including risk factors, operative mortality, major complications, and other outcomes. Herbert and coworkers⁷ found complete correlation in only 2% of cases, 1 to 10 discrepancies in 82% of cases, and more than 10 fields of disagreement in 17% of cases.⁷ This study did not examine other types of operations or etiology of disease. The assessment of accuracy of this database was performed by a database supervisory person who may have followed internal rules or guidelines, and thus may not have demonstrated the same variability as if they had used "untrained" abstractors.

The STS's database has undertaken several initiatives to ensure the quality of data. Most of these efforts, however, have been limited to logic checking, missing data, and outliers.⁸ An example of logic checking would include patient death during the initial hospitalization with a blank date of death; software prevents record completion until the date is entered. In addition, data managers at each submitting site are given data quality reports noting inconsistent data, missing data, and extreme data. Centers may resubmit their data as many times as required. None of these measures, however, assess the accuracy of the data submitted.

There have been comparisons of data submitted to the STS database by all centers in the state of Iowa and data available in administrative datasets such as the Medical Provider and Analysis Review Part A public use data files.⁹ In an analysis, Welke and coworkers⁹ found that there were more cases of isolated CABG operations entered in the STS NCD than in the Medical Provider and Analysis Review database. Welke and coworkers⁹ suggested that institutions are submitting more complete data to STS NCD than to other administrative databases; however, this was a crude assessment. Mack and colleagues¹⁰ similarly examined the correlation between administrative data and clinical data from the Medical City Hospital in Dallas. Their study found poor agreement between databases but attributed this to calendar year versus fiscal year, populations reported, date used for the patient record captured, and the definition of mortality. These studies are examples of the variability in the completeness of data and the comparability of data among databases, but they did not assess the variability present within individual data elements in the STS NCD. Variability among databases draws into question the reliability of the content of each database being compared.

The STS has begun to conduct national audits on the accuracy of the data in the NCD. Their stated goal is to audit 20 centers per year for 62 data elements in 20 cases of isolated CABG. Preliminary results were presented at the Advances in Quality and Outcomes Conference in October 2008 on

140 cases audited at 17 centers in 2008, along with results from an audit in 2007. Variables that had perfect agreement in both 2007 and 2008 included age, sex, admission date, discharge date, and date of operation. At least 22 variables, however, had less than 90% agreement in either 2007 or 2008. Unfortunately, the patient status at 30 days (dead or alive) was only in agreement in 83% of cases in 2008. This is of great concern, because "30-day mortality" or "operative mortality" is the most common outcome used for both quality indicators and research. It is notable that there was an average increase in the percentage agreement of $33\% \pm 22\%$ from 2007 to 2008. There were no data given, however, on the method of selection of cases at an institution, the selection of the institutions for the audit, the types of original cases, and the distribution of variables therein. Thus although the results provide reason for concern, it is difficult to interpret them in a broader context. It is to be hoped that this auditing process will be expanded, and the results should be made available to all participating institutions. This should be done in a nonpunitive manner, but the results may significantly affect the cardiac surgical community's perception of quality control measures and research done with the database. The STS NCD has begun to implement a strategy of a "virtual patient."¹¹ In this situation, sample records are abstracted by data managers at various centers. These results of this "virtual patient" abstraction can be used to determine the adequacy of definitions. There are, however, no publicly available data concerning these results. It would also be important for the STS to provide more detailed guidelines outlining where and when data should be collected from the patient record. Recording the date and precise source of the data would allow more accurate comparisons.

Our study is limited by using a single institution with a limited number of abstracted cases, and our resultant confidence intervals were large. Our results may also be dependent on the distribution of operations that were selected. In addition, our abstractors were cardiac surgeons in training, who could arguably be either underqualified or overqualified to complete this type of data abstraction. The STS advocates point-of-care data entry, however, and suggests in its participation manual that residents, perfusionists, and nurse clinicians contribute to data collection.¹ We also limited our abstraction to diagnostic and operative variables and did not assess preoperative risk factors, outcome measures, or the completeness of the number of cases abstracted, because others have specifically focused on the abstraction of these variables.^{4,7,10}

The STS NCD is a powerful tool in cardiovascular surgery for quality assessment and clinical research. We demonstrated some of the potential variability in the abstraction of data for this national database. Caution must be exercised when using data from the STS NCD, or any other clinical data set, without knowledge of the variability of the data contained therein.

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COMMENTARY

Data variability and validity: The elephant in the room

Gary L. Grunkemeier, PhD, and Anthony P. Furnary, MD

The Society of Thoracic Surgeons (STS) National Adult Cardiac Surgery Database (NCD), begun in 1989, has found almost universal acceptance, with more than 1000 cardiac surgery programs currently participating. Cardiac surgery has been a leader in this effort, with worldwide acknowledgment, and is no doubt the envy of other surgical specialties. Only now, 20 years later, for example, is orthopedic surgery attempting to create a national registry, motivated by a 4-year, \$12 million grant from the Agency for Healthcare Research and Quality.¹ Not only is cardiac surgery ahead of the pack, it is far ahead.

BROWN AND COLLEAGUES

This issue of the *Journal* contains an article questioning the NCD data validity.² The objective of this article was "to determine the variability of disease etiology and operative data elements in the STS database when abstracted by untrained physician abstractors." These untrained abstractors, 4 cardiac residents and fellows, assessed 28 objec-

tively quantifiable preoperative and intraoperative variables. The result was "variable agreement among untrained data abstractors in the STS database"; specifically, there was agreement only approximately 89% (median) of the time (range 42%–100%).

The STS urges participants to acquire a part-time or full-time specialist to manage the NCD, a Data Manager (DM), and provides description of the qualifications for the job and ideas of where to look for a suitable candidate.³ So, because the STS database is populated primarily with the results from DMs, of more interest would be a cross-validation study among DMs, not untrained physicians. Apparently there are 5 DMs at Mayo (Brown and colleagues² use the term "Professional Data Abstractor" in this article, but we use DM in conformance with STS terminology). It would have been of more relevance to measure the agreement among the DMs. If those results were not consistent, we could conclude that STS needs to make its data definitions more clear or publish more in-depth data abstraction rules.

PROVIDENCE HEALTH & SERVICES EXPERIENCE

We represent a collaborative of all 12 cardiac surgery units in the Providence Health & Services hospital system, located in 5 western states. Since 1997, we have collected data prospectively on a common data form, sent the data to a coordinating center for merging and auditing, and

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