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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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then prepared quarterly reports summarizing and comparing providers. We initially designed our own data forms and produced our own risk-adjustment models, but because all 12 hospitals have become NCD participants, we have converted to using STS data elements and risk-adjustment models. Thus, we *do* have independent DMs and could perform the more relevant study alluded to. Although we have not done such a formal study, our 12 DMs work closely together and have periodic conference calls and webinars dedicated to data definition and quality issues. Our DMs send duplicate files of their STS data submissions to our central coordinating center, which, in addition to comparing surgical outcomes among hospitals, also compares the distributions of all variables across all facilities. We have found there is wide variability among the DMs in assessing those many variables that are even more subjective than those examined in the study by Brown and colleagues,² such as the percentage and degree (New York Heart Association class) of congestive heart failure, angina type (stable/unstable), cardiac presentation, and renal failure. When large deviations are found, a conference call is convened in which the DMs and 1 or more cardiac surgeons clarify STS definitions and coding and discuss abstracting “rules.”

This has had many advantages but still is not perfect because we do not have control over the data elements and data definitions, which at times breeds frustration among our DMs. The purpose in this editorial is to mention some of these data issues.

VARIABLE DEFINITIONS AND INTERPRETATIONS

In response to a request for specific input for this editorial, one DM gave an example concerning permanent stroke (Comps-Neuro-Stroke Perm), whose current definition is “any confirmed neurologic deficit of abrupt onset caused by a disturbance in cerebral blood supply that did not resolve within 24 hours.” Many believe that 24 hours is too short to determine the permanence of a stroke; it was 72 hours in the past, and, internally, we continue to use the former definition. Another issue concerns what should be included as a stroke. The STS FAQ document⁴ contains these 2 conflicting entries:

- Q.** If the patient experiences confusion, delirium, or encephalopathic events that resolve within 72 hours, is that considered Stroke Permanent? (February 2008)
- A.** Neurologic deficits such as confusion, delirium, and anoxic or metabolic encephalopathy are not coded as stroke.
- Q.** Should metabolic and anoxic encephalopathy be coded as stroke permanent? (December 2009)
- A.** The physician leadership stated to capture these patients as “complications stroke permanent.”

Frustration with resolving such issues is exemplified by these DM comments: “Unfortunately, if you submit a clinical

question to the STS, the time to response is dismal. I currently have a question unanswered regarding how to code pleural effusions as the primary reason for readmission. I submitted the question 6 months ago, still no response.... When I sent my question out to the national STS data managers group via e-mail, I received an e-mail saying that it was an inappropriate use of the site and that the question should be referred to the STS FAQs. (I had already done that.)”

PROVIDENCE HEALTH & SERVICES AUDITS

STS-approved software provides Consistency Edits and Consistency Checks,⁵ but we have found that the centrally submitted STS data from our member institutions still contains omissions and inconsistencies. Therefore, before using this STS data for our own internal continuous quality improvement, we apply a series of additional audits that flag and return submissions to the 12 sites for resolution. The data conflicts that trigger these additional flag-setting audits include the following:

- inconsistencies among the 4 STS variables for death (mortality, operative death, discharge status = dead, status at 30 days after surgery = dead);
- status at 30 days after surgery = alive (dead) and the days to death calculated from the dates of procedure and death is less than (more than) 30 days;
- complication = yes with no supporting complication(s) given;
- readmit reason = infection-deep sternum, but complication-deep sternal = no;
- inconsistencies between surgical incidence and prior cardiovascular intervention;
- postoperative length of stay more than 30 days, but readmission within 30 days = yes;
- unrealistically high or low values of certain key variables (surgery time, length of stay, body mass index, hematocrit); and
- missing key variables (reason for readmission, mortality date).

CONCLUSIONS

The STS NCD is accepted worldwide as the premier example of a superb clinical outcomes database and is the envy of other surgical societies. It is evolving and improving, in large part because of the efforts of the dedicated, professional DMs who continue to provide critical feedback. We thank Drs Brown, Leno, and Schaff, for offering this article in that same spirit of constructive criticism. It is our collective job as surgeons, administrators, DMs, and statisticians working within this demanding and high-risk specialty to contribute to this interactive process of continuous quality improvement for the betterment of our patients and the health care system as a whole.

STS Data Managers from the following facilities participate in the Providence Health & Services Cardiovascular Disease Study Group (PHS-CDSG):

Alaska: Providence Alaska Medical Center (Anchorage).

Washington: Providence Regional Medical Center Everett; Providence St. Peter Hospital (Olympia); Providence Sacred Heart Medical Center & Children's Hospital (Spokane).

Oregon: Providence Portland Medical Center; Providence St. Vincent Medical Center (Portland); Providence Medford Medical Center.

California: Providence St Joseph Medical Center (Burbank); Providence Holy Cross Medical Center (Mission Hills); Providence Little Company of Mary Hospital (Torrance); Providence Tarzana Medical Center.

Montana: St. Patrick Hospital and Health Sciences Center (Missoula).

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