What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report of the STS Congenital Database Taskforce and the Joint EACTS-STS Congenital Database Committee

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The most concrete and universal outcome measure used in databases, whether governmental, professional society, research, or third-party payer, is operative mortality. To assure congruous data entry by multiple users of The Society of Thoracic Surgeons and the European Association for Cardiothoracic Surgery congenital heart surgery databases, operative mortality must be clearly defined. Traditionally, operative mortality has been defined as any death, regardless of cause, occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation. Differing hospital practices result in problems in use of the latter part of the definition (eg, the pediatric hospital that provides longer-term care will have higher mortality rates than one which transfers patients to another institution for such care). In addition, because of the significant number of pediatric multiple operation hospitalizations, issues of assignment of mortality to a specific operation within the hospitalization, calculation of operative mortality rates (operation based vs patient admission based), and discharge other than to home must be addressed and defined. We propose refinements to the definition of operative mortality which specifically meet the needs of our professional societies' multi-institutional registry databases, and at the same time are relevant and appropriate with respect to the goals and purposes of administrative databases, government agencies, and the general public.

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In the field of cardiothoracic surgery, accurate reporting and analysis of outcomes are increasingly fundamental expectations. While the debate goes on with respect to which performance metrics should or must be utilized, it is inescapable that the most concrete and universal outcome measure is operative mortality.

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Operative mortality has been traditionally defined as any death, regardless of cause, occurring (1) within 30 days after surgery in or out of the hospital and (2) after 30 days during the same hospitalization subsequent to the operation [1]. The demand for accurate data reporting and outcomes analysis has resulted in numerous data acquisition systems organized by governmental agencies, professional specialty societies, and third-party payers. The mortality definitions used by these systems are not standardized. The once standard definition has metamorphosed into many variations, thus resulting in confusing and conflicting data aggregations.

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The objective of this article is to examine the historic and extant definitions of operative mortality and to refine the definition of operative mortality specifically to meet the needs of our professional societies' multi-institutional registry databases, and at the same time to be relevant and appropriate with respect to the goals and purposes of administrative databases, government agencies, and the general public.

Background

In 2000, a common nomenclature and database for congenital heart surgery was published by the International Congenital Heart Surgery and Database Project [2]. This dataset, which has been adopted by both The Society of Thoracic Surgeons (STS) and the European Association for Cardiothoracic Surgery (EACTS), defined the two mortality measures for The STS and The EACTS Congenital Databases: (1) operative mortality and (2) mortality assigned to this operation.

The term operative mortality was defined in the traditional fashion previously referenced. Mortality assigned to this operation was proposed as a database field to deal with the problem of reoperations during the same hospital admission. With traditional systems it is possible to assign death to all operations occurring during the same admission; such assignment would increase the overall mortality inappropriately. With use of the field mortality assigned to this operation, a patient undergoing multiple operations during a given hospitalization would have the field operative mortality answered yes for each operation; but, the field mortality assigned to this operation would be answered yes for only one operation. The surgeon assigns the operative mortality to the most appropriate operation.

Although operative mortality and mortality assigned to this operation were defined by The EACTS and The STS [2, 3], these data fields could not be utilized during the subsequent analysis of the data in the second (2002), third (2003), and fourth (2004) harvests of The STS Congenital Database [4–9] because incomplete data entry prevented reliable statistical analysis. Only mortality prior to discharge was consistently reported; therefore, these data harvest reports presented analyses based on mortality prior to discharge.

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In quantifying death as a percentage occurrence within a population, both a numerator and a denominator are necessary. In this article we will closely examine the choice of numerator and denominator and its impact on the final measure quantifying death.

Numerator

The numerator in the fraction quantifying death represents the number of patients considered dead. Mortality prior to discharge and 30-day status are two examples resulting in different counts of mortality.

Mortality prior to discharge has the advantage of being easy to measure. However, two disadvantages of this measurement exist. First, patients may die in the hospital several months after a given operation, with death arising from reasons unrelated to the preceding surgery. Second, outcome reporting based on mortality prior to discharge can be misleading in instances in which patients are transferred to a different institution so that the mortality occurs at another hospital or rehabilitation facility. The measured 30-day status has the advantage of being less subject to multiple interpretations when compared with mortality prior to discharge. Nevertheless, some centers state that they are unable to report a 30-day status because they do not have the resources to track mortality after discharge, especially for patients referred from remote locations. Furthermore, the potential exists to affect outcome reporting by unnecessarily prolonging the life of a clearly dying patient so that death occurs on day 31 rather than on day 30. The latter presumes a feedback loop between the collected data and medical decisions, an effect of which the size is unknown, but nonetheless is not likely to be zero.

The EACTS–STS definition of operative mortality, as previously defined, has the advantage of being the time-honored standard definition of mortality. This definition combines features of mortality prior to discharge and 30-day status. Consequently, the potential disadvantages of this definition include the disadvantages of both mortality prior to discharge and 30-day status.

An alternative approach [7] is to report mortality prior to discharge only within 30 days of surgery. This definition designates any death occurring within 30 days of surgery prior to discharge. Although this reporting system solves the problem relating to late noncardiac deaths after patent ductus arteriosus (PDA) ligation in premature infants, it results in underreporting of mortalities that are clearly related to surgery.

The case can be made that it is the moral responsibility of every surgeon to track 30-day mortality after discharge, even with respect to patients referred from remote locations. Detailed analyses of some subgroups of patients have shown that the duration of the early hazard function describing risk of death extends beyond the period of hospitalization. It has been argued that mandatory tracking of 30-day mortality after discharge may not be appropriate or feasible for a multi-institutional outcomes database (registry). In a time of limited resources, this task may be both difficult for some institutions and not justifiable because of the small number of patients dying after discharge but within 30 days. Although additional time and money is required, the value gained from this investment is substantial. The authors of this article believe that it is the responsibility of every surgeon to employ a comprehensive quality assurance program [10, 11]. Therefore, documentation of the patient status 30 days postoperatively (alive or dead) will be required in order to submit data to the EACTS and STS databases.

The patient who has had multiple operations in a given hospitalization raises the next issue related to the numerator in the fraction quantifying death. The STS currently employs the rule that "mortality that occurs for a patient with multiple admissions is assigned to the latest admission," and "mortality that occurs for an admission with

Table 1. Operation-Based Versus Patient-Based Mortality

Operation-Based Mortality	All Patients	Age 0 to 28 days	Age 29 days–1 year	Age Older than 1 year
Eligible operations	20,400	4,618	6,645	9,137
Discharge mortality	825	487	202	136
Discharge mortality (%)	4.0%	10.5%	3.0%	1.5%
Patient Admission-Based Mortality	**All Patients**	**Age 0 to 28 days**	**Age 29 days–1 year**	**Age Older than 1 year**
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%

multiple operations is assigned to the first operation during that admission" [6]. Occasionally the first operation of a given hospital admission may not be the most appropriate operation to assign the mortality; nevertheless, we now believe that less error will result from the application of this rule (ie, assigning mortality to the first operation of an admission) than from a policy that allows the individual surgeon or other data entry personnel to choose the operation to which a given mortality is assigned.

The ideal information about mortality is not mortality prior to discharge or 30-day status, but rather mortality over the long-term as defined by a hazard function curve or Kaplan-Meier curve. Unfortunately, tracking this type of mortality over the long-term has not yet been achieved in a multi-institutional cardiac surgery registry database. Tracking long-term mortality has been limited to individual institutional comprehensive databases or academic type multi-institutional databases focusing on specific subgroups, such as the database of the Congenital Heart Surgeons' Society.

Denominator

The denominator in the fraction quantifying death can be the count of (1) the number of operations performed, or (2) the number of patients treated, or (3) the number of patient admissions with patients undergoing surgery.

An operation-based operative mortality calculation is generated using a numerator representing the number of patients who have died and a denominator representing the number of operations performed. In the circumstances of a patient undergoing multiple operations in a given hospitalization, this operation-based mortality calculation results in an imperfect depiction of mortality because the mortality is diluted across many operations instead of being assigned to 1 patient.

A patient-based operative mortality calculation also uses a numerator representing the number of patients who have died, but a denominator representing the number of surgical patients. This methodology may not truly measure programmatic surgical performance when a single patient requires several complex staged surgical reconstructions during separate admissions separated by several months or years.

A patient admission-based operative mortality calculation also uses a numerator that represents the number of patients who have died, but a denominator that represents the number of surgical patient admissions rather than surgical operations or surgical patients. Any patient admission that includes one or more cardiac operations of operation types of "CPB" or "No CPB Cardiovascular" will add to the denominator. (CPB is cardiopulmonary bypass.) A patient admission-based mortality calculation will result in a mortality calculation higher than an operation-based mortality calculation. Table 1 compares identical data from the 2004 STS Congenital Database harvest [6] using first operation-based mortality and then the patient-admission based mortality.

Comment

Death must be clearly defined in any multi-institutional registry database. In a Veterans Affairs study of patients undergoing coronary artery bypass surgery (n = 15,288 patients; 43 hospitals), ranking of hospital performance varied substantially depending on the definition of death utilized [1].

In the future, The EACTS and The STS Congenital Database Reports will account for operative mortality utilizing its traditional definition [1]. Having adopted this time-honored definition, we suggest additional rules to address some specific issues that we have encountered (see Appendix). Required changes in data entry should be minimal because these refinements of operative mortality are calculated during the data analysis process using the extant congenital heart surgery minimum dataset.

Finally, interpretation of outcomes research is difficult without verification of the completeness and accuracy of the data. Verification of data completeness is crucial because it has been previously shown that patients not included in medical audit have worse outcomes than those included [12]. The importance of the verification of data accuracy has been demonstrated in both the United Kingdom Central Cardiac Audit Database [13] and the EACTS Database [14]. Mortality data verification by both external data audit employing source data verification

[14] and independent comparison with data from different sources such as death registers [13] needs to be further "explored as a means of improving the ascertainment of surgical complications, including death" [15]. The definition and measurement of death has profound moral and ethical implications [16]. It is our professional responsibility to engage in self-evaluation, in part by employing "voluntary sharing of data for the expressed purpose of improved patient care" [17]. Still, "unselfish sharing of data and free exchange of ideas" [17] will be meaningless without a standardization of definitions.

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Appendix

Rules to Define Operative Mortality

1. In the future, the EACTS and The STS Congenital Database Reports will report *Operative Mortality* defined as any death, regardless of cause occurring (1) within 30 days after surgery in or out of the hospital, and (2) after 30 days during the same hospitalization subsequent to the operation
2. If a patient had more than one operation during a hospitalization, assignment of mortality is made to the first operation of the given hospitalization that meets the criteria of an operation type that will be included in the overall programmatic mortality analysis as described in Rule number 10. This operation that would be assigned the mortality can be called the "index operation." (Previously, no useful data was obtained when we allowed the individual surgeon or other data entry personnel to choose the operation to which a given mortality is assigned. We now believe that better data will be obtained by assigning mortality to the first operation of an admission. In the future, algorithmically driven assignment of mortality to the most complex case of the admission might further minimize assignment errors.)
3. The EACTS and STS Congenital Database Reports will employ *patient admission-based operative mortality calculation*. The numerator is the number of patients who have died as measured by the criteria of *Operative Mortality*. The denominator is the number of surgical patient-admissions. Any patient admission that includes one or more cardiac operations of operation types "*CPB*" or "*No CPB Cardiovascular*" will be considered a "cardiovascular surgical admission" and add to the denominator. (Rule number 10 below clarifies which interventions will actually be counted as operations in the EACTS-STS Congenital Database mortality calculations.) It should be noted that the patient who dies after admission but before any surgery will not count as an operative mortality and therefore will not count when calculating patient admission-based operative mortality, unless the patient had prior surgery within 30 days (of the mortality) and is readmitted to the hospital in which case the patient would count as an operative mortality of the prior index operation as described in Rules number 1 and 2 above.
4. Any mortality that occurs for a patient with multiple cardiovascular surgical admissions is assigned to the latest cardiovascular surgical admission. Each cardiovascular surgical admission will be treated as an independent observation. For example, a given patient will contribute only 1 encounter to the total denominator for the single hospitalization for the Norwood (Stage 1) operation even if that particular hospitalization involves multiple operations. If this same patient is discharged home and is later re-admitted and undergoes a superior cavopulmonary connection operation more than 30 days after the Norwood (Stage 1), this patient will now contribute 2 encounters (observations) to the de-

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nominator. However, if a patient is readmitted to the hospital and undergoes surgery within 30 days of a prior index operation, mortality is assigned to the earlier index operation.

5. In order for a record to be complete and eligible for mortality analysis, the following database fields must be complete:
   A. Date of Admission
   B. Date of Surgery
   C. Operation Type ("CPB," "No CPB Cardiovascular," "ECMO," "Thoracic," "Interventional Cardiology," or "Other" in the minimum dataset. [CPB is cardiopulmonary bypass and ECMO is extracorporeal membrane oxygenation]. Software vendors may supply other operation types [eg, "CPB Standby," "CPS," "Minor Procedure," "Bronchoscopy," "Other Endoscopy," where CPS is Cardiopulmonary support]; these are converted by the vendor during data harvest export to the appropriate operation type from the official list of choices. For example, operations coded as "Minor Procedure" are converted by the vendor during data harvest export to Operation Type "Other.")
   D. Primary Diagnosis
   E. Primary Procedure
   F. Discharge Status (Alive or Dead)
   G. 30-day Status (Alive or Dead).

   A record cannot be included in the mortality analysis until both Discharge Status and 30-day Status fields are completed.
6. Patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will not be included in the mortality calculation in the EACTS and The STS Congenital Database reports. (We acknowledge that mortality after surgical PDA closure in low-birth weight premature infants can be related to surgical judgment or technique; however, the vast majority of deaths in this patient population are multifactorial and largely unrelated to the surgical procedure in time and by cause. Therefore, because mortality in this patient group could potentially impact significantly on the expression of overall programmatic mortality, we have decided to exclude from mortality analysis patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure.)
7. If a patient was admitted from their home, they must be either dead or discharged to home prior to completing the field discharge status. If a patient was admitted from their home, the field discharge status can not be completed if the patient is transferred to another acute care facility or chronic care facility until they are either dead or discharged to home. However, if this patient survives in a chronic care facility for 6 postoperative months (ie, 183 postoperative days), the patient can then be considered "alive" in the discharge status field. (Some institutions may not have a setup that allows transfer to a chronic care facility and instead utilizes their own institution as the chronic care facility. If an institution does not utilize a chronic care facility and instead keeps these chronic patients in-house, this institution can apply to this Rule [number 7] whenever one of their patients survives for 6 postoperative months (ie, 183 postoperative days) on "chronic care status" within their institution.)
8. If a patient was admitted from (ie, transferred from) a chronic care facility where they chronically reside, they must be either dead or discharged either to home or to a chronic care facility prior to completing the field discharge status.
9. If a patient was admitted from (ie, transferred from) another acute care facility, Rule number 7 as previously stated applies if they lived at home prior to their admission to the transferring acute care facility. If a patient was transferred from another acute care facility, Rule number 8 as previously stated applies if they lived in a chronic care facility prior to their admission to the transferring acute care facility.
10. Only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included in the overall programmatic mortality analysis. (All cases classified as operation "*CPB*" and "*No CPB Cardiovascular*" will be included in the mortality analysis except for patients weighing less than or equal to 2,500 g undergoing PDA (patent ductus arteriosus) ligation as their primary procedure, as discussed in Rule number 6 above, and organ procurement cases, as discussed in Rule number 11 below).
11. Operations coded as operation type "*CPB Standby*" will be converted to operation type "*No CPB Cardiovascular*" by the software vendor prior to analysis, with two exceptions: (1) Pectus repair procedure coded as "*CPB Standby*" should be converted to operation type "*Thoracic*" and (2) purely bronchoscopic procedures coded as "*CPB Standby*" should be converted by the vendor to operation type "*Bronchoscopy*" if it is an available option, or by the vendor to operation type "*Thoracic*." (Centers and surgeons may use cardiopulmonary bypass standby or ECMO standby when performing the Nuss pectus repair or complex bronchoscopic interventions. While other "*CPB Standby*" operations are converted appropriately to operation type "*No CPB Cardiovascular*" by the software vendor prior to analysis, these two examples are best not analyzed as "*No CPB Cardiovascular*" cases in the mortality analysis.) Lung transplantation employing CPB will be coded as such, whilst lung transplantation without CPB will be coded as "*No CPB Cardiovascular*." Organ procurement is coded as operation type "*No CPB Cardiovascular*," but will be excluded from both the numerator and the denominator in all mortality analysis.
12. Operation types "*ECMO*," "*Thoracic*," "*Interventional Cardiology*," and "*Other*" will not be included in the overall programmatic mortality analysis. Minor procedures, such as central line placement procedures or arterial line placement procedures and similar vascular access procedures, will count as operation type "*Other*" and will not be included in the overall programmatic mortality analysis.
13. When measuring both programmatic volume and programmatic mortality, only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included. When measuring both programmatic volume and programmatic mortality, Operation types "*ECMO*," and "*Thoracic*," "*Interventional Cardiology*" and "*Other*" will not be included. Therefore, minor procedures such as central line placement procedures will not be included in programmatic volume or mortality measurements. Although organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the mortality analysis, they will be included in programmatic volume measurement. Thus, only Operation types "*CPB*" and "*No CPB Cardiovascular*" will be included in the mortality analysis; and as stated above, organ procurement and patients weighing less than or equal to 2,500 g undergoing PDA ligation as their primary procedure will be excluded from the numerator and the denominator of the mortality analysis.