What is Operative Morbidity? Defining Complications in a Surgical Registry Database*

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Executive Summary

During the last 2 decades, mortality after surgery for congenital heart disease has decreased dramatically and is now 4% in several large multicenter studies [1–6]. To allow for complete evaluation of quality of care in the field of congenital heart surgery, alternative methodologies must be developed that go beyond mortality or adjusted mortality to include morbidity assessment. The European Association for Cardio-Thoracic Surgery (EACTS) and The Society of Thoracic Surgeons (STS) Congenital Heart Databases, two of the most widely used tools to report and evaluate quality of care in congenital heart surgery, are the ideal platforms upon which may be developed a systematic characterization of operative morbidity.

The STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee previously defined operative mortality [7, 8] and herein address various terms relating to operative complications to arrive at a standardized terminology that would find broad acceptance among database users. Also addressed are the time intervals that delineate intraoperative and postoperative complications, as well as measurable indices of morbidity, such as length of postoperative intubation. Certain potentially important measures are problematic because of institutional variation in practice patterns (eg, intensive care unit stay). For this reason, the Task Force is disposed to prefer terms and intervals that are less subject to individual institutional protocols.

We define the term *complication* to be a universal term, encompassing both events related to the disease process and events related to healthcare interventions. In previous reports that address quality of care and patient safety, investigators have chosen to focus on a variety of related terms that fall under the broad categorization of complications [9–14]. It is important to acknowledge fundamental differences between *medical errors*, *adverse events*, and *iatrogenesis*. *Medical errors* can be the cause of adverse events; however, not all adverse events or complications result from or are associated with medical error. *Adverse events* are complications, but by convention they encompass those complications associated with a healthcare intervention and a suboptimal outcome. Whereas *iatrogenesis* actually encompasses all of the consequences of healthcare interventions (both positive and negative), the connotation is typically negative. Accordingly, we suggest the use of the alternate term *iatrogenic complications* to describe complications that are associated with a healthcare intervention. The terms, iatrogenic complications and adverse events, are not synonymous because all adverse events are associated with suboptimal outcome, whereas not all iatrogenic complications are associated with suboptimal outcome. A synonymous term for "adverse events" is "medical injury," which has acquired such a negative connotation that it may be

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misleading and inflammatory. We suggest that this term has no utility and should be retired.

The STS Congenital Heart Surgery Database Specifications (version 2.50) define a complication as: "A departure from the desired postoperative course. This includes the time period up until hospital discharge. It also includes the time period after discharge if the event is attributable to the cardiac surgical procedure performed" [15]. Members of The STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee now propose a modified definition (ie, *a complication is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause, or be associated with, suboptimal outcome).*

This new definition of the terms does not include any time interval descriptors or statement regarding causality. Causality will not be addressed in this report. However, we have defined the *period of data collection*: (1) up to 30 days after operation if the patient has been discharged from the hospital or (2) until the EACTS-STS Congenital Database Discharge Date if a patient is still in the hospital after 30 days. The rules to determine the EACTS-STS Congenital Database Discharge Date are presented in Figure 1. Finally, because the time intervals we have defined mandate that some complications can occur after transfer to another hospital or after hospital discharge, institutions who wish to specifically track the subset of complications that occur within their own facility can do so by simply adding an optional field to the database to document the institutional location of any complication.

Members of The STS Congenital Database Task Force participated in refining all definitions offered in this article by telephone conferences, e-mail correspondence, and meetings; all participating members reviewed and approved the final definitions in this report. By standardizing the terminology for operative complications, the tools that are necessary to study and quantify morbidity are created. These tools may ultimately allow investigators to create a quantitative morbidity metric to be used to evaluate institutional performance and quality of care. In addition, multi-institutional outcomes analysis will have increased meaning, outcomes analysis will become relevant to multiple disciplines, and lesion-based comparative studies will become more powerful when the definition of complication is universal.

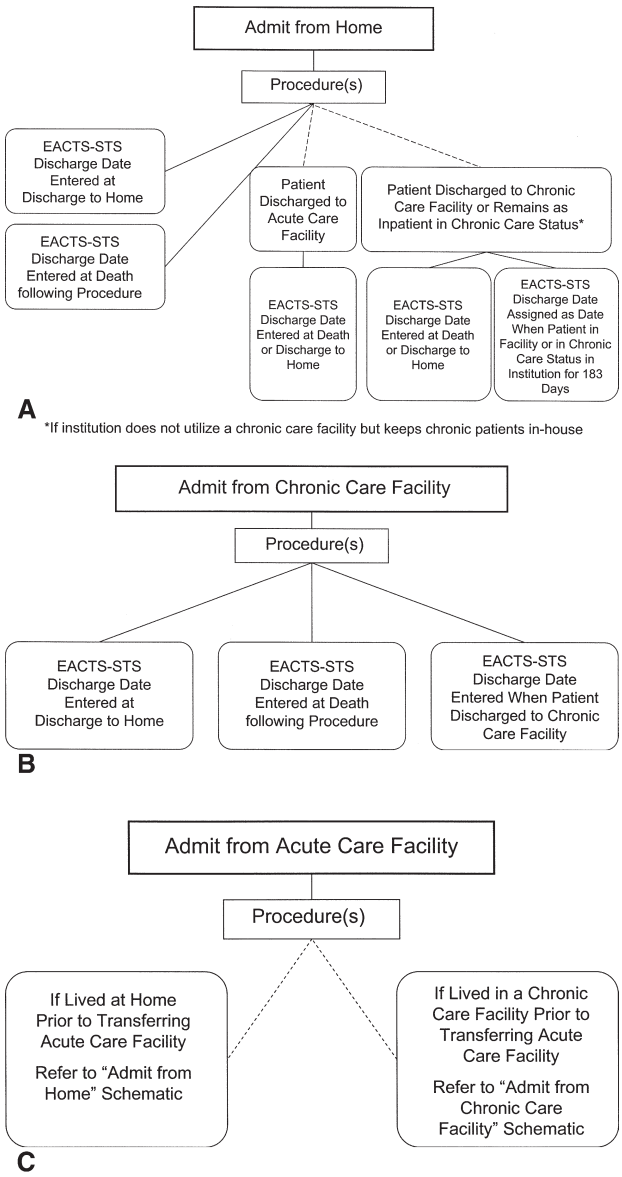

Fig 1. Determination of the European Association for Cardio-Thoracic Surgery and The Society of Thoracic Surgeons (EACTS-STS) Discharge Date when patient is (A) admitted from home, (B) transferred from a chronic care facility, or (C) transferred from an acute care facility. Dashed lines indicate intervening conditions that must be met before the EACTS-STS Discharge Date can be entered.

Introduction

Complications may be caused by a patient's underlying disease state, healthcare interventions, or a combination of the two. Complications associated with surgical procedures or interventions may include consequences or events associated with the procedure that adversely affect the patient's prognosis. These can include worsening of the severity of the disease, development of new or accentuated signs and symptoms, or the creation of new pathologic changes involving either the cardiovascular system or other organ systems. Such adverse effects of surgical treatment, such as abnormal, harmful, undesired, or unintended outcomes, need not necessarily be unexpected. Medical knowledge of a disease, treatment, or procedure usually entails an understanding of the most common complications so that these complications can be foreseen, prevented, or at least recognized easily and expeditiously.

Surgical intervention is generally associated with a predictable course of recovery that can be modified by actions, omissions, or events that can lead to the prevention or delay of such recovery. This unanticipated delay also may be considered to be a complication of the

surgical intervention. Many congenital cardiovascular anomalies are associated with coexisting abnormalities of other organ systems (congenital, secondary to, or coincident with the cardiovascular disease); it follows that an exacerbation or worsening of these coexisting medical conditions, when it occurs in the setting of a surgical intervention, is in fact a complication of the surgical intervention. Patient genotype may also influence the likelihood or severity of some complications (eg, angiotensin converting enzyme genotype, monocyte expression of HLA-DR).

Based on the previously noted information, we offer the following definitions:

Definitions

Morbidity is a state of illness or lack of health that includes physical, mental, or emotional disability. Morbidity can occur without complication. For example, a 6-day-old full-term neonate undergoes an arterial switch operation, is extubated on postoperative day 1 and is discharged home on postoperative day 5, whereas an 18-day-old full-term neonate undergoes an arterial switch operation, is extubated on postoperative day 5, and is discharged home on postoperative day 10. Both patients are discharged home in excellent condition and neither had complications. However, the second infant manifested more morbidity than the first, as measured by a longer period of mechanical ventilatory support, a longer hospital stay, and increased resource consumption (ie, morbidity without complication). *Operative morbidity* is the temporary or permanent disability observed during and after an operation. In The STS and EACTS Congenital Heart Databases, operative morbidity is defined as any morbidity that occurs during the time interval between OR Entry Date and Time and the end of the period of data collection. (See Appendix 1 for applicable definitions of time intervals). Importantly, the most successful operation is still associated with some degree of temporary disability. Therefore, an operation with zero morbidity is impossible to achieve, whereas an operation without complications may be achievable.

All disease states have intrinsic morbidity; in addition, a disease state can have complications associated with the underlying illness, as well as complications associated with healthcare interventions. A patient with pneumonia can have morbidity without complication (eg, fever and shortness of breath necessitating antibiotics and possibly hospitalization to treat the "uncomplicated" pneumonia), morbidity with complication related to the underlying disease (eg, parapneumonic empyema), or morbidity with complication related to a healthcare intervention (eg, anaphylactic reaction to antibiotics).

A *complication* is an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause or be associated with suboptimal outcome. A complication does not necessarily represent a breech in the standard of care that constitutes medical negligence or medical malpractice.

A *medical error* is a healthcare intervention that may be an act of commission or omission in which a planned action fails to be completed as intended, or the use of a wrong plan is implemented to achieve an aim; this event is a departure from the desired course of events, is less than ideal, and may cause or be associated with suboptimal outcome. Not all complications are caused by medical error. Medical error does not necessarily imply negligence or malpractice, and such errors may be latent within the system of care rather than solely the responsibility of the medical practitioner [16, 17].

An *adverse event* is a complication that is associated with a healthcare intervention and is associated with suboptimal outcome. Adverse events represent a subset of complications. Not all medical errors result in an adverse event; the administration of an incorrect dose of a medication is a medical error, but it does not always result in an adverse event. Similarly, not all adverse events are the result of a medical error. A child may develop pneumonia after an atrial septal defect repair despite intraoperative and perioperative management that is free of error. Complications of the underlying disease state that are not related to a medical intervention are not adverse events. For example, a patient who presents for medical care with metastatic lung cancer has already had a complication (ie, metastatic spread) develop as a result of the primary lung cancer without any healthcare intervention. Furthermore, complications that are not associated with suboptimal outcome or harm are not adverse events and are known as *no harm events*. The patient who receives an incorrect dose of a medication without harm has experienced a no harm event, but not an adverse event.

The literal meaning of *iatrogenesis* is "brought forth by a healer," and in its original form does not have a negative connotation. Whereas all events caused by the healthcare delivery team fall under the heading of iatrogenesis, only an event that is a departure from the desired course of events, and may cause or be associated with suboptimal outcome, is an *iatrogenic complication*.

The time intervals associated with complications are crucial in understanding the dynamic nature of these processes. Various intervals may be used to analyze complications, and the EACTS and The STS Congenital Heart Databases' definitions for these intervals are presented in Appendix 1. Briefly, an *intraoperative complication* is any complication that occurs or is recognized during the time interval between the database field, OR Entry Date and Time, and the database field, OR Exit Date and Time. A *postoperative complication* is any complication that occurs or is recognized during the time interval between OR Exit Date and Time and the end of the period of data collection. An *operative complication* is any complication that occurs during the time interval between OR Entry Date and Time and the end of the period of data collection, and thus includes both intraoperative and postoperative complications. In the next upgrade of the EACTS-STS Database Specifications, the

database field Postoperative Event (short name: Complication) will be renamed Operative Complication. The proposed newly defined field, Operative Complication (*an event or occurrence that is associated with a disease or a healthcare intervention, is a departure from the desired course of events, and may cause or be associated with suboptimal outcome*), may occur temporally during the period of data collection while the patient's care may be overseen by multiple services (eg, cardiovascular surgery, cardiology, intensive care, neonatology, anesthesia); thus, complications are noted irrespective of service management (see Appendix 2 for definition of *period of anesthetic care*).

Comment

The STS Congenital Database Task Force fully supports the efforts of the National Quality Forum to standardize the taxonomy of patient safety [18]. By standardizing the technique for measuring operative and postoperative complications, one creates the tools necessary to measure, study, and quantify morbidity. However, such tools rely not only on consistency of definitions, but also on accurate and reliable data. It is recognized that certain potentially important measures, such as length of postoperative intensive care unit stay, can be problematic and even misleading because of institutional variation in practice patterns. Lacour-Gayet and colleagues [19] are currently undertaking the evaluation of a morbidity index based on three measurable elements: (1) postoperative length of stay; (2) postoperative length of time until final extubation; and (3) permanent complications, such as stroke, permanent dialysis-dependent renal failure, and permanent heart block requiring a pacemaker [19]. Although most significant operative complications can be measured by their contribution to ventilation time and length of stay, the occurrence of complications associated with either severe temporary disability (eg, unplanned reoperation, extracorporeal membrane oxygenation, and so forth) or permanent disability (eg, atrioventricular block requiring pacemaker, dialysis-dependent renal failure, and so forth) deserve additional recognition in the quantification of morbidity with a morbidity index [19]. Clearly, more extensive research is needed to quantify morbidity and validate these concepts.

Finally, interpretation of outcomes research is difficult without verification of the completeness and accuracy of the data. It has been shown that patients not included in medical audits have worse outcomes than those included [20]. The importance of data accuracy verification has been demonstrated in both the United Kingdom Central Cardiac Audit Database [21] and the EACTS Database [22, 23]. Mortality data verification, by either an independent comparison from other sources such as death registries [21] or source data verification by an external data audit [22], needs further exploration [24]. Morbidity data verification is equally important and perhaps more difficult to implement. It is our professional responsibility to engage in this self-evaluation [25], and participation in surgical registries such as the EACTS-STS Congenital Heart Databases is one means by which this may be done by surgeons. Still, such participation is meaningless without standardization of definitions [26, 27].

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Appendix 1

Time Intervals Used in the EACTS and The STS Congenital Heart Databases

1. OR Entry Date and Time

The date and time to the nearest minute (using a 24-hour clock) that the patient entered the operating room (OR). If the procedure was performed in a location other than the OR, record the time when the sterile field, or its equivalent, was set up.

2. OR Exit Date and Time

The date and time to the nearest minute (using a 24-hour clock) that the patient exited the operating room. If the procedure was performed in a location other than the OR, record the time when the sterile field or its equivalent was taken down.

3. Operating Room Time (OR Time)

The calculated interval between the time the operation begins and the time the operation ends. The interval begins at OR Entry Time and ends at OR Exit Time (ie, definition 2 minus definition 1).

4. Skin Incision Date and Time

The time to the nearest minute (using a 24-hour clock) that the skin incision or its equivalent was made (eg, during bronchoscopy, one would use the bronchoscope insertion time).

5. Skin Closure Date and Time

The time to the nearest minute (using a 24-hour clock) that the skin incision was closed or its equivalent (eg, removal of bronchoscope). If the patient left the operating room with an open incision, collect the time that the dressings were applied to the incision.

6. Procedure Time

The calculated interval between the time the procedure began and the time that the procedure ended. The interval begins at Skin Incision Start Time and ends at Skin Closure Time (ie, definition 5 minus definition 4).

7. Hospital Admission Date

The date the patient was admitted to the hospital. For those patients who originally entered the hospital for an outpatient capacity procedure (eg, preoperative catheterization), but then are not discharged, the admit date is the date of the patient's entry into the hospital.

8. EACTS-STS Discharge Date

The date of discharge is determined by three rules (see Fig 1A–C). These rules specify how to complete the field, EACTS-STS Discharge Date, and are consistent with previously published rules defining Operative Mortality and how to complete the field, Discharge Status (Alive or Dead) [7]. These rules also apply to the rare instances of transfers from the hospital where surgery occurs to other chronic or acute care facilities.

9. EACTS-STS Length of Stay

The EACTS-STS length of stay for a hospitalization is the interval between the hospital admission date and the EACTS-STS Discharge Date (definition 8 minus definition 7).

10. EACTS-STS Postoperative Length of Stay

The calculated interval between the date the operation ended (as indicated by the OR Exit Date and Time) and the EACTS-STS Discharge Date (definition 8 minus definition 2).

11. Hospital Discharge Date

The date the patient was discharged from the hospital where the surgery took place. In situations in which the patient was discharged to another acute care facility or to a chronic care facility, the Hospital Discharge Date is the date the patient is transferred from the hospital where the surgery took place to another facility. In rare instances, the Hospital Discharge Date differs from the EACTS-STS Discharge Date, which is addressed in Figure 1A–C.

12. Hospital Length of Stay

The interval between the Hospital Admission Date and the Hospital Discharge Date (definition 11 minus definition 7).

13. Hospital Postoperative Length of Stay

The interval between the date the operation ended (as indicated by the OR Exit Date and Time) and the Hospital Discharge Date (definition 11 minus definition 2).

14. Intubation Date and Time

The date and time (using a 24-hour clock) that ventilatory support started [15]. Specific guidelines are offered in The STS Database Specifications (version 2.50) [15] that address issues such as tracheostomy in place at admission, patient intubated at admission, unintended extubations, elective tube changes, and unknown intubation date and time, among others.

15. Initial Extubation Date and Time

The date and time (using a 24-hour clock) that ventilatory support initially ceased after surgery. Specific guidelines are offered in The STS Database Specifications (version 2.50) [15] that address issues surrounding extubation time for the tracheostomy patient, the patient who expires while intubated, and the patient discharged on chronic ventilatory support, among others.

16. Final Extubation Date and Time

The date and time (using a 24-hour clock) that ventilatory support last ceased prior to discharge after surgery. Specific guidelines are offered in the STS Database Specifications (version 2.50) [15] that address issues surrounding final extubation time for the tracheostomy patient, the patient who expires while intubated, and the patient discharged on chronic ventilatory support, among others.

17. Postoperative Length of Time Until Initial Extubation

The interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Initial Extubation Date and Time (definition 15 minus definition 2).

18. Postoperative Length of Time Until Final Extubation

The interval between the time the operation ended (as indicated by the OR Exit Date and Time) and the Final Extubation Date and Time (definition 16 minus definition 2).

19. Postoperative Length of ICU Stay

The interval between admission to the intensive care unit (ICU) after surgery and the final ICU discharge.

Appendix 2

Of special note, the *period of anesthetic care* is the time interval that begins when the anesthesia team assumes responsibility for patient care (either at OR Entry Date and Time or at the time when the patient is picked up by the anesthesia team from another unit in the hospital) and ends either:

1. when the anesthesia team relinquishes responsibility for patient management (ie, when the patient is turned over to the postoperative care team, commonly the ICU team); or
2. at the time of discharge from the recovery room (if the patient is transported to the recovery room) or when another healthcare team assumes responsibility for the patient; or
3. when report is given to the intensive care unit nurses, in instances in which the anesthesiologist is also the intensivist.

In addition, *the period of anesthetic care* includes any time spent in the preoperative period during which the patient is being evaluated by the anesthesia care team.