The Theory, Practice, and Future of Process Improvement in General Thoracic Surgery

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Process improvement, in its broadest sense, is the analysis of a given set of actions with the aim of elevating quality and reducing costs. The tenets of process improvement have been applied to medicine in increasing frequency for at least the last quarter century including thoracic surgery. This review outlines the theory underlying process improvement, the currently available data sources for process improvement and possible future directions of research.

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Process improvement, in its broadest sense, is the analysis of a given set of actions with the aim of elevating quality and reducing costs. The origins of much of what have become the principles of process improvement had its origin within manufacturing and engineering. Essential to process improvement is the objective measure of performance characterized by the collection, analysis, and reporting of information pertaining to the performance of an individual, group, organization, or system.

The tenets of process improvement have been applied to medicine in increasing frequency for at least the past quarter century. Health insurers seeking an estimation of the value of the health care, government organizations hoping to reduce the cost of health care, and clinicians with the desire to study their results have all applied the concepts of process improvement to various areas of medicine and surgery. However, such efforts, with notable exceptions, have lacked coordination, commonality, and meaning.

Process improvement in health care is often referred to by the vernacular term "quality." Medical quality, as defined by the Institute of Medicine in 1990, is the degree to which health care systems, services, and supplies for individuals and populations increase the likelihood for positive health outcomes and are consistent with current professional knowledge.[1] The latter is described as "best practice" or "evidence-based practice" and may include the use of national guidelines constructed by specialty organizations, national cooperatives, and health systems.

Although several quality of care frameworks exist including the World Health Organization–recommended Quality of Care Framework and the Bamako Initiative, the Donabedian model continues to be the most commonly encountered paradigm for assessing health care quality.[2-4] Avedis Donabedian, a physician and health services researcher at the University of Michigan, developed this model in 1966. According to the Donabedian model, information about quality of care can be drawn from 3 categories of measures: structure, process, and outcomes. Structure describes the context in which care is delivered including providers, facilities, financing, and equipment. Process denotes the transactions between patients and providers throughout the delivery of health care. Finally, outcome refers to the effects of health care on the health status of patients and populations.

A fourth category of metric termed intermediate outcomes has become increasingly more common in the field of medical process improvement.[5] These outcomes are measures of clinical conditions that do not directly reflect patients' quality or quantity of life. Examples are blood pressure or lipid control. Such variables are often more easily and timely measured than the true outcome in question such as coronary artery disease in these examples. Intermediate outcomes are also referred to as surrogate outcomes and require confirmation that they reliably relate to the true outcome being considered.

Any discussion of metrics requires consideration of validity. In measurement theory, validity represents the extent to which a given measure actually

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captures what it is supposed to measure.[6] Within health care quality, 2 corollaries exist. First, process or structural metrics are valid only if improved performance on the given variable actually results in better health outcomes. The second is that the relationship between the measured, often surrogate, metric and the true outcome needs to be valid. Lastly, for a given measure of quality for a provider to be valid, it must be, in some significant amount, under the provider's control.[7]

CURRENT ENVIRONMENT

Within the specialty of noncardiac or general thoracic surgery, several ongoing national initiatives exist, which have been designed to assess and improve quality. Each of these systems relies on the underlying principles of the Donabedian quality framework in which surrogate metrics denoting the concept of quality for a given procedure or disease are identified, measured, and compared. The other major force in the specialty for quality assessment is scholarly investigations of specific procedures or disease processes using regional, national, and international administrative databases. It is important to the discussion of process improvement in general thoracic surgery to understand the attributes and limitations of these databases when reviewing the findings of what is a growing genre of literature. The following is a synopsis of the more common data sources relevant to general thoracic surgery.

CLINICAL DATABASES

Society of Thoracic Surgeons General Thoracic Surgery Database

The most recognized database within the specialty is the Society of Thoracic Surgeons (STS) General Thoracic Surgery Database initiated in 2002. Based on the unprecedented success of the Society for Thoracic Surgery's Adult Cardiac Surgery Database, this database currently represents more than 371,000 submitted cases. The database is administered through the Duke University Clinical Research Institute.

The General Thoracic Surgery Database is organized around data sheets submitted for each major thoracic surgery procedure a program performs. Data are harvested and analyzed twice each year.

The database is not only used to compare raw outcome data between programs but also to create models that allow the risk adjustment of morbidity and mortality for specific procedures such as lobectomy or esophagectomy. Site auditing of database submissions has also been initiated to validate submitted information. Efforts also continue to use data elements from the database for the Physician Quality Reporting System and for the data to be submitted electronically.

Criticisms of this database are that most participating institutions are tertiary referral hospitals or sites for cardiothoracic residency training programs or both and that few, if any, general surgeons participate. The former criticism may result in the database containing a population of patients with significant comorbidities or who require a complex surgical procedure, which could confound the conclusions of analysis. It is currently estimated that general surgeons perform most noncardiac surgeries in the United States.[8] Hence, the latter criticism implies that a significant proportion of general thoracic surgery cases are not captured for analysis, and in the era of minimally invasive esophagectomy and lobectomy, the traditional procedures may be underrepresented.

STS Database Risk Models: Predictors of Mortality and Major Morbidity for Lung Cancer Resection[9]

Background

The aim of this study is to create models for perioperative risk of lung cancer resection using the STS General Thoracic Database (GTDB).

Methods

The STS GTDB was queried for all patients treated with resection for primary lung cancer between January 1, 2002, and June 30, 2008. Three separate multivariable risk models were constructed (mortality, major morbidity, and composite mortality or major morbidity).

Results

There were 18,800 lung cancer resections performed at 111 participating centers. Perioperative mortality was 413 of 18,800 (2.2%). Composite major morbidity or mortality occurred in 1612 patients (8.6%). Predictors of mortality include the following: pneumonectomy ($P < 0.001$), bilobectomy ($P < 0.001$), American Society of Anesthesiology rating ($P < 0.018$), Zubrod performance status ($P < 0.001$), renal dysfunction ($P = 0.001$), induction chemoradiation therapy ($P = 0.01$), steroids ($P = 0.002$), age ($P < 0.001$), urgent procedures ($P = 0.015$), male gender ($P = 0.013$), forced expiratory volume in 1 second ($P < 0.001$), and body mass index ($P = 0.015$).

Conclusions

Thoracic surgeons participating in the STS GTDB perform lung cancer resections with a low mortality and morbidity. The risk-adjustment models created have excellent