

# Blazing new trails: initial efforts to create a joint Society of Thoracic Surgeons-European Society of Thoracic Surgeons (STS-ESTS) dataset

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**Abstract:** Over the past 5 years, there has been an increased focus on international database collaboration between the Society of Thoracic Surgeons (STS) General Thoracic Surgery Database (GTSD) and European Society of Thoracic Surgeons (ESTS) Registry Task Forces. To this end, a joint STS-ESTS database Task Force meeting is held each year at the STS annual meeting, during which current and future projects are discussed. As this relationship has evolved, various issues have been encountered that must be overcome to maximize the potential of this collaborative effort. This article provides an overview of the STS GTSD and ESTS Registry, past projects, and the challenges faced by the Societal Task Forces as future projects are envisioned.

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## Introduction

The Society of Thoracic Surgeons General Thoracic Surgery Database (STS GTSD) and European Society of Thoracic Surgeons (ESTS) Registry were independently developed for the same purposes: quality improvement, institutional benchmarking, and surgeon education. Over the past 5 years, there has been an increased focus on international database collaboration between the STS GTSD and ESTS Registry Task Forces. To this end, a joint STS-ESTS database Task Force meeting is held each year at the STS Annual Meeting, during which current and future projects are discussed. As this relationship has evolved, various issues have been encountered that must be overcome to maximize the potential of this collaborative effort. This article provides an overview of the STS GTSD and ESTS Registry, past projects, and the challenges faced by the societal task forces as future projects are envisioned.

## The STS GTSD and ESTS Registry

The STS GTSD is the largest general thoracic surgery

database in existence (1). It is a voluntary database that provides participants with bi-annual, risk-adjusted reports benchmarking institutional performance against national outcomes. The STS GTSD has collected data on more than a half million operations from nearly 1,000 surgeons, including a small number of international participants over the past 15 years. Duke Clinical Research Institute (DCRI) serves as the data warehouse for the STS GTSD and a voluntary task force, led by Benjamin Kozower, MD, provides oversight of the data. Annual audits of the STS GTSD have routinely demonstrated agreement rates of >95% with hospital charts, validating the accuracy and completeness of the database (2). The STS GTSD has recently started to collect 5-year survival data on patients and has linked to governmental claims databases in an effort to increase the utility of the database (3).

Updates to the STS GTSD data collection form are made every 3 years, with the most recent revision (version 2.4) went live on January 1, 2018. With version 2.4, a number of modifications were made, including the addition of optional thymus/mediastinal mass, tracheal resection,

and hiatal hernia/gastroesophageal reflux disease (GERD) sections. Only suspected or diagnosed lung and esophageal cancer resections are mandatory in version 2.4. An additional change this year is the shift from biannual batch uploads to a continuous data submission process. In late 2018, participant site dashboards will be available to provide real time examination of participant data and quality measures, including individual physician dashboards.

The STS GTSD Task Force has used the data to update risk models for lung resection and esophagectomy for cancer (4,5). This allows observed:expected (O:E) morbidity and mortality ratios to be reported back to individual participating institutions. In addition, composite quality measures for lobectomy for lung cancer and esophagectomy for esophageal cancer have been created (6,7). These performance measures are made widely available on the STS public reporting website, where patients can go to compare outcomes of participating institutions (8). For ease of use by the public, hospitals are designated as 1-, 2-, or 3-star programs based on their risk-adjusted outcomes.

Launched in 2007, the ESTS Registry is an international, voluntary database that collects data from nearly 200 European and non-European participants. Similar to the newly upgraded STS GTSD, the ESTS Registry is organized into modules focused on various surgical procedures. The ESTS Registry contains a central lung resection module in addition to thymic, mesothelioma, neuroendocrine tumor, and chest wall surgery modules. Data are de-identified and uploaded to an online platform that is managed by an external company (K-Data Clinical; Rome, Italy). The system is capable of receiving data uploads from both individual institutions and national registries, as occurs with the French and Hungarian National Registries. Although the ESTS is not formally audited, the ESTS registry task force has performed repeated quality analysis assessments to optimize the accuracy of the submitted data (9,10). Like the STS GTSD, risk models for performing lung resections and a composite performance score have been developed and are used for comparing the outcomes of participating institutions (11,12). In both the ESTS Registry and STS GTSD, participants have access to their own data for quality improvement and research purposes, but data from the entire database are only accessible after approval of a formal proposal.

### Collaboration between the databases

Given the similar purpose and general organization of the

ESTS Registry and STS GTSD, collaboration between the databases task forces seemed like a natural fit. In 2012, the first joint meeting between the STS GTSD and ESTS Registry Task Forces was held and has since occurred yearly at the STS Annual Meeting. The first attempts at comparison of the ESTS Registry and STS GTSD were limited by variation in the data points collected and their specific definitions. Therefore, the STS GTSD and ESTS Registry Task Forces worked to harmonize the databases, producing a list of more than 60 variables with a standardized, agreed upon definitions (13). This harmonization allowed the first study comparing variation in treatment practices and outcomes between the STS and ESTS in patients who underwent pulmonary resection (14). Although some intercontinental variation was expected, the differences in outcomes observed suggested an opportunity for ongoing quality improvement. This study acted as a catalyst for future investigation, including examining stage-specific, risk-adjusted outcomes to better understand the intersocietal variation. However, since that project in 2016, multiple challenges have arisen as the creation of a joint dataset containing de-identified patient-level data from the ESTS and STS has been pursued.

### Blazing new trails

Having the ability to combine patient subsets from the STS GTSD and ESTS Registry for comparison and analysis would make numerous studies possible. However, to pursue these projects, a number of necessary steps must be taken. The patient population and variables of interest must be determined, all definitions must be uniform, and the completeness of the data elements in each database must be considered (15). Thus far, these initial steps have not proven as challenging as the drafting of the initial international data transfer agreement (DTA) outlining how a new data repository containing patient level data from both societies would be populated, maintained, analyzed, interpreted, and reported.

The first study that has been proposed requiring the creation of a joint STS-ESTS dataset would involve pooling data from both societies to examine the hypothesis that surgical resection, including pneumonectomy, when performed as part of a multi-modality regimen for stage IIIA (N2) non-small cell lung cancer (NSCLC), is associated with low rates of perioperative morbidity and mortality. Creating a joint database for this purpose would generate important, large-scale, current perioperative outcome data

that may differ from historical reports.

To date, the STS GTSD and ESTS Registry Task forces have had extensive discussions, but a formal DTA has yet to be signed. Many questions have been encountered as the task forces move forward together into this new, uncharted territory. It has been preliminarily suggested that the ESTS would export de-identified patient-level data to the STS, and all data analysis would be performed by DCRI. However, some of the issues that have arisen include ensuring that the privacy laws of different countries are abided by when data are exported across international boundaries. In this case, it has been proposed that the ESTS would be the data exporter and data controller, meaning that ESTS would ensure that data are legally collected and processed according to European legislation.

It is also unclear how to address differences among jurisdictions from which data originate regarding the de-identification of medical records. Although not yet formally decided between the STS and ESTS, the European Union (EU) working party of the Data Protection European Authorities has given its opinion on de-identification techniques (16). They concluded that de-identification techniques can provide privacy guarantees as long as the context and objectives of the de-identification process are clearly set out to achieve the targeted de-identification while producing useful data. They determined that the optimal solution should be decided on a case-by-case basis, possibly by using a combination of different techniques, while taking into account the practical recommendations developed by the working party. In this case, the ESTS, as the data controller, would likely be responsible for determining the optimal de-identification techniques.

Another question that has been raised is how secure transfer of patient level data across international boundaries should be performed? This issue has been robustly addressed by the Privacy Shield, an agreement signed in 2016 between the EU and the U.S. granting protection of personal data transferred from the EU to certified U.S. organizations (17). This framework was created by the U.S. Department of Commerce and European Commission to provide companies on both continents with a mechanism to comply with EU data protection requirements when transferring personal data from the EU to the U.S. It requires transparency on how companies use personal data, strong governmental oversight, and increased cooperation with EU data protection authorities.

Once a combined STS-ESTS database is created, there remain uncertainties regarding what controls should be

placed upon the use of the data. A DTA between the STS and ESTS will need to address this issue and may reference the standard clauses approved by the European Commission in 2001 (16). These clauses generally relate to the data importer abiding by a set of guidelines ensuring that they are able and willing to fulfill their obligations to the data exporter, maintain good communication, and lay out processes in the event that sub-processing of the data is requested or required.

The STS-ESTS DTA must also define who will own the combined STS-ESTS dataset once it is established. The STS GTSD and ESTS Registry generally agree that the patients own their personal health information, however participants give the STS and ESTS ownership of the aggregate data. Perhaps a reciprocity clause providing both the ESTS and STS ownership of the combined dataset would be appropriate. Furthermore, expectations for balanced visibility of both societies in publications and presentations produced from the merged database should be established (same number of co-authors, presentations at both annual meetings, etc.) Finally, it should be agreed upon what will happen to the merged dataset once an individual project is completed or the societal collaboration ends. Can it be used for additional agreed upon projects or should it be destroyed?

## Conclusions

There are often more questions than answers when new ground is being broken. A combined STS-ESTS dataset has not been created in the past; no precedent exists and no templates to work from are available. There is certainly interest on the part of both the STS GTSD and ESTS Registry Task Forces in overcoming the barriers that have arisen. It is widely recognized that we, as an international community of thoracic surgeons, have the responsibility to use the data that we have collected to its greatest potential. Having the ability to create combined datasets from the STS GTSD and ESTS Registry will allow numerous new studies to be performed, with the overarching goal of improving thoracic surgical care worldwide. It is an exciting time as new trails are blazed and templates are forged that will be used for future collaborative efforts between the STS GTSD and ESTS Registry Task Forces.

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## Footnote

*Conflicts of Interest:* The author has no conflicts of interest to declare.

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