Supporting Statement – Part B

The TVT Registry

Collections of Information Employing Statistical Methods

1. All patients undergoing the procedure will have the STS/ACC TVT Registry completed by a designated person at the facility performing the procedure. The number of patients is estimated to be 14,871 annually. All patients undergoing the procedure will be asked to complete the Kansas City Cardiomyopathy Questionnaire (KCCQ-12). The number of patients is estimated to be 14,871. No sampling of the study population will occur. The response rate for the registry is around 99.5% and for the KCCQ-12 is around 90%.

2. There is no statistical methodology for stratification and sample selection. The estimate of patients meeting the clinical criteria to undergo the procedure is 14,871 annually. Twenty percent of the data is audited by the NCDR. Registry data will be collected at the time the patient undergoes the procedure only. KCCQ-12 data collection will occur prior to when the patient undergoes the procedure, 30 days after the procedure and one year after the procedure.

3. All patients undergoing the procedure will be entered into the registry and administered the KCCQ-12 by a designated person at the facility performing the procedure and at 30 days and one year office visits with their managing physician. Data entry is required for receipt of payment.

4. The data variables for the registry include most of the variables in other NCDR sponsored registries. Therefore, the data collection procedures and methods have been tested for the registry data. The KCCQ-12 Is used to measure patient outcomes in research.

5. There are no statistical aspects of the design and thus, no one was consulted on statistical aspects of the design. When CMS issues a National Coverage Decision (NCD), all conditions specified in that NCD become requirements for payment under 1862(a)(1)(E). Since this stems from an NCD (see https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257), data from all patients receiving a TAVR must entered into the registry for payment to be made. The entity responsible for the data collection and analyses is The STS/ACC TVT Registry. The STS/ACC TVT Registry is being administered by the American College of Cardiology National Cardiovascular Data Registry (ACC\NCDR). The 30 day and one-year post procedure data collection will occur at the office of the physician responsible for management of the patient.

6. CMS is conducting an intramural analysis of long-term outcomes related to the TAVR procedure. This differs from the research being carried out using the registry data by outside researcher because it uses claims data. It will thus an analysis of the universe of Medicare beneficiaries receiving the device. Outcomes to be evaluated include: stroke; all-cause mortality; transient ischemic attacks (TIAs); and repeat aortic valve procedures.