

Supporting Statement – Part A

The TVT Registry

A. Background

The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, “Transcatheter Aortic Valve Replacement (TAVR)”. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we must formally reopen and reconsider the policy. We are continuing to review and analyze the data collected since this NCD was effective in 2012.

CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry supports a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis. The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the ACT.

The data also includes the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-12) to assess health status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.

The data will be analyzed to not only critically evaluate each patient’s quality of life pre and post TAVR (minimum 1 year) but also address at least one of the following questions:

- What is the incidence of stroke?
- What is the rate of all cause mortality?
- What is the incidence of transient ischemic attacks?
- What is the incidence of major vascular events/
- What is the incidence of acute kidney injury?
- What is the incidence of repeat aortic valve procedures?

The conduct of the STS/ACC TVT Registry and the KCCQ-12 is pursuant to Section 1142 of

the Social Security Act (the ACT) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1) (A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

B. Justification

1. Need and Legal Basis

CMS has determined that TAVR is only reasonable and necessary when data is collected to examine two key outcomes of treatment are 1.) periprocedural and long-term risk of stroke or death, 2.) health-related quality of life and function post-TAVR. The first outcome of interest will be addressed through an analysis of the STS/ACC TVT registry. The second outcome of interest will be addressed through an analysis of the KCCQ-12.

2. Information Users

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the ACT. Furthermore, data from the Registry assists the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, The TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data is made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. A list of publications that have used these data is available at <https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/tvt-registry-aug-2015-ncdr-published-manuscripts.pdf?sfvrsn=2>.

3. Use of Information Technology

The TVT Registry data and KCCQ-12 data are submitted using a web-based data collection tool provided by the ACC and STS to enter the data. Microsoft Internet Explorer Version 7 or higher is required to submit data through the TVT Registry web-based data collection tool. The data collection forms for the TVT Registry and the KCCQ-12 are available on the NCDR website.

4. Duplication of Efforts

This is an extension of an existing PRA package. Prior to this policy, there was not data collection of this nature. The TVT Registry was developed in collaboration with the FDA, CMS, and the following professional societies: the Society for Cardiovascular Angiography and Intervention, the American Association for Thoracic Surgery. Further, it was designed to capture the same data on all future TAVR devices.

5. Small Businesses

The collection of information does not impact small businesses or other small entities.

6. Less Frequent Collection

The Registry data is collected when the patient meets the criteria for the TAVR. The KCCQ-12 is administered prior to when the patient receives the device, 30 days and 1 year post procedure. The data is collected 3 times so that we can determine whether the procedure improves patient quality of life and physical function. If the data is not collected at these three points in time, CMS is not be able to assess key outcomes of interest and determine what factors predict clinically meaningful net health benefits and harms.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published March 18, 2016. There were no public comments received. The 30-day Federal Register notice published June 17, 2016 (81 FR 39644). There were no public comments received. During the national coverage analysis for this NCD which commenced in 2011, CMS collaborated with the STS, ACC, and FDA on the development and selection of the data collected in the Registry and through the KCCQ-12.

9. Payments/Gifts to Respondents

There will be no payments or gift to respondents. When claims are submitted they must include information identifying which registry or trial the beneficiary participated in on the claim which demonstrates adherence to the NCD requirements necessary for Medicare coverage. If this identification is not made on the claim, then the claim cannot be processed and paid. Data entry is required by the registry and is thus necessary to meet the NCD requirements and Medicare payment to providers and facilities.

10. Confidentiality

Patient identifiers are collected to facilitate creation of an analytical data file comprised of registry data, KCCQ-12 data and Medicare claims data – The TAVR Medicare Research File.

CMS has an information exchange agreement (CAG 2012-001) with the Society of Thoracic Surgeons and the American College of Cardiology Foundation that is in compliance with the Privacy Act of 1974. Any publications resulting from the analyses of these data will be based on aggregate data and therefore not identify individual patients, providers or facilities as a result of data collection required by CMS. See 70 FR 53667. SYSTEM NO. 09-70-0547, SYSTEM NAME: “Data Collection Secondary to Coverage Decision (DCSCD) System, HHS/CMS/OCSQ.”

11. Sensitive Questions

No questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that we commonly considered private will be collected through the STS/ACC TVT Registry or the KCCQ-12.

12. Burden Estimates (Hours & Wages)

The TVT Registry takes data entry personnel 56 minutes to complete at the time the procedure is being performed at an in-patient facility. There are eight pages of variables. The 56 minutes for completion was estimated by determining that seven minutes per page were required to enter the data. Based on the data from procedures performed in 2013, 2014 and through November 2015, and a response rate of 99.5%, an average of 14,871 TAVR procedures were performed each year. Based on this average, we estimate that 14,871 registry forms will be completed one time only over one year yielding an annual burden of 13,830 hours. According to the National Cardiology Disease Registry staff, nurses usually enter the data electronically. According to the U.S. Department of Labor (https://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for a nurse in 2016 was \$32.70. To account for overhead and benefits we have doubled the mean hourly wage which is equal to \$69.40. Fifty-six minutes to enter the data is 93% of an hour which is \$64.54. The annual cost burden is thus calculated as $\$64.54 \times 14,871 = \$959,774$.

The KCCQ-12 takes beneficiaries seven minutes to complete the eight questions at each of three data collection periods (baseline, 30 days post procedure, and one year post discharge from the hospital). The seven minutes for the beneficiary to complete the KCCQ was determined from published literature on this patient-completed instrument. Fourteen thousand eight hundred seventy-one respondents will complete the questionnaire three times over one year yielding an annual burden of 5,354 hours. According to the U.S. Department of Labor, the mean hourly wage for a nurse in 2016 was \$32.70 and doubled to account for overhead and benefits to equal \$69.40. Seven minutes to enter the data is 12% of an hour which is \$8.33. The annual cost burden is thus calculated as $\$8.33 \times 44,613 = \$371,626$.

13. Capital Costs

The initial fee to participate in the TVT Registry for the first calendar year is \$25,000 and the annual fee for subsequent years is \$10,000 per year.
(<https://www.ncdr.com/TVT/Home/Default.aspx>)

14. Cost to Federal Government

We anticipate that Grade 14 Step 1 Federal employee will spend 60 hours a year overseeing this endeavor with the TVT Registry. The locality adjusted wages for a CMS employee at that Grade and Step is \$112,021 annually as of 2017. Thus, the annual cost to the Federal government of overseeing the TVT Registry is \$3,2221.

15. Changes to Burden

The changes to burden are due to calculations based on averages of the actual number of TAVR procedures performed since the original PRA package was created. The original numbers were estimates that were not based on experience as these were new processes at the time.

16. Publication/Tabulation Dates

All TVT data will be linked to Medicare claims data to be able to observe TAVR patient outcomes over time. Most analyses of the data will use longitudinal regression methods. The TVT Registry has a STS/ACC Research and Publications Subcommittee to oversee research and publication activities. The analysis of the data will result in multiple peer-reviewed publications. The 2016 Annual Report of The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry is available from the Journal of the American College of Cardiology, volume 69, 2017 in pages 1215-1230 and includes relevant publications.

17. Expiration Date

The expiration date, OMB control number and disclosure statement will be included on the data collection forms.