Supporting Statement – Part A

The Transcatheter Valve Therapy (TVT) Registry

A. Background

The data collection is required by the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation" and was previously entitled "Transcatheter Mitral Valve Repair (TMVR)". Effective January 19, 2021, CMS updated this NCD to expand coverage to functional mitral regurgitation (MR). Previously, coverage was limited to degenerative MR. To more precisely define the treatment addressed in this NCD, we replaced the term TMVR with TEER. The TEER 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 the original NCD was effective in 2014 and following the update in 2021.

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 TEER for mitral valve regurgitation. The TVT Registry supports a national surveillance system to monitor the safety and efficacy of the TEER technologies for the treatment of MR. The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TEER is reasonable and necessary (e.g., improves health outcomes) for Medicare beneficiaries under section 1862(a)(1)(A) of the Act.

The data will also include 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 critically evaluate each patient's quality of life pre and post TEER for mitral valve regurgitation (minimum1 year) and patient, practitioner and facility level variables that predict the following outcomes:

- Stroke
- All-cause mortality
- Repeat TEER or other mitral procedures
- Transient Ischemic Attacks (TIAs)
- Major vascular events
- Renal complications
- Functional capacity
- Quality of Life (QoL)

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 TEER for mitral valve regurgitation is only reasonable and necessary when data is collected to examine two key outcomes of treatment are 1.) periprocedual and long-term risk of stroke or death, 2.) health-related quality of life and function post-TEER. 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 TEER 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 will assist 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 mitral regurgitation. For purposes of the TEER NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. A list of publications that have used these data is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/february2018ncdrpublishedmanuscriptsbyregistry.pdf?sfvrsn=30d1d99f_24.

3. Use of Information Technology

The TVT Registry data and KCCQ-12 data will be submitted using a web-based data collection tool provided by the ACC and STS to enter the data. Microsoft Internet Explorer Version 9.0 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 related devices.

5. Small Businesses

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

6. Less Frequent Collection

The Registry data will be collected when the patient meets the criteria for the TEER. The KCCQ-12, a questionnaire that assess patient health status, functioning, and quality of life, 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 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 July 2, 2021 (86 FR 35300). There were no public comments received.

The 30-day Federal Register notice published September 24, 2021 (86 FR 53059).

During the first national coverage analysis for this NCD which commenced in 2013, CMS collaborated with the Society of Thoracic Surgeons, American College of Cardiology, 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 for researchers to create analytical data files comprised of registry data, KCCQ-12 data and data from other relevant sources, for example ResDAC. The TVT Registry website states the following regarding confidentiality: "Patient, hospital and physician confidentiality is always protected. All projects are supervised by the TVT Registry R&P committee to ensure adherence to data access and use policies and procedures, as well as relevant regulations." (https://www.ncdr.com/WebNCDR/tvt/publicpage/research)

11. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

We estimate that the TVT Registry takes data entry personnel 90 minutes to complete at the time the procedure is being performed at an in-patient facility. There are 12 pages of variables. Previously, the minutes for completion were estimated by determining that seven minutes per page were required to enter the data. We note that the current version of the TVT Registry includes numerous changes from the prior version which we believe adds time beyond the previously estimated seven minutes per page. To account for the time needed for users to acquaint themselves with the changes in the current version, we estimate that it will take 7.5 minutes per page to enter the data for a total of 90 minutes. Based on the data from procedures performed in 2018, 2019 and 2020, an average of 8,649 TEER procedures were performed each year. Based on this average, we estimate that 8,649 registry forms will be completed one time only over one year yielding an annual burden of 12,974 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 2020 was $38.47. To account for overhead and benefits we have doubled the mean hourly wage which is equal to $76.94. Ninety minutes to enter the data is 150% of an hour which is $115.41. The annual cost burden is thus calculated as $115.41 x 8,649 = $998,181.

The KCCQ-12 form will take 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. Each of the 8,649 respondents will complete the questionnaire three times over one year yielding an annual burden of 3,027 hours. According to the U.S. Department of Labor, the mean hourly wage for a nurse in 2020 was $38.47. To account for overhead and benefits we have doubled the mean hourly wage which is equal to $76.94. Seven minutes to enter the data is 12% of an hour which is $9.23. The annual cost burden is thus calculated as $9.23 X 25,947 = $239,491.

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 $11,330 per year. (https://www.ncdr.com/TVT/Home/Default.aspx)

14. Cost to Federal Government

We anticipate that a Grade 14 Step 1 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 $122,530 annually or $58.71 hourly as of 2021. Thus, the annual cost to the Federal government of overseeing the TVT Registry is $3,523.

15. Changes to Burden

The changes to burden are due to calculations based on increases in the time required to complete the TVT Registry form, increases in mean wages since 2017 and averages of the actual number of TEER procedures performed in 2018, 2019 and 2020.

The TVT Registry form has been replaced with a new version that has had numerous changes including major changes in content, terminology and organization that are too voluminous to itemize. For example, the History and Risk Factor section was restructured by moving the location/order of sub-sections. Within sub-sections, the location/order of data elements was reorganized and some data elements were moved to different sub-sections. Additionally, the responses for some data elements were expanded adding content (i.e. from yes/no to selecting from six response options with subsequent data elements).

The increase in the annual number of TEER procedures performed is representative of the evolving field and providers growing more comfortable with performing and providing the services. The respondents increased from 3,897 to 8,649. The burden hours increased from 4,092 to 12,974 for TEER. The total burden hours increased from 5,456 to 16,001.

16. Publication/Tabulation Dates

A list of publications that have used data from the TVT Registry is available at https://www.ncdr.com/WebNCDR/docs/default-source/tvt-public-page-documents/february2018ncdrpublishedmanuscriptsbyregistry.pdf?sfvrsn=30d1d99f_24. Research using TVT Registry data is ongoing and subsequent publications are released regularly.

17. Expiration Date

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