EXPERT TASK FORCES' STATEMENT

Minimum Core Data Elements for Evaluation of TAVR

A Scientific Statement by PASSION CV, HVC, and TVT Registry

Matheus Simonato, MD,[a],* Sreekanth Vemulapalli, MD,[b],* Ori Ben-Yehuda, MD,[c,d] Changfu Wu, PhD,[e]
Larry Wood, MBA,[f] Jeff Popma, MD,[g] Ted Feldman, MD,[f] Carole Krohn, MPH,[h] Karen M. Hardy, BS, RHIA,[i]
Kimberly Guibone, DNP,[j] Barbara Christensen, MSHA, RN,[k] Maria C. Alu, MS,[d] Shmuel Chen, MD,[l] Vivian G. Ng, MD,[l]
Katherine H. Chau, MD,[l] Bahira Shahim, MD, PhD,[d] Flavien Vincent, MD,[d] John MacMahon, MSE,[m] Stefan James, MD,[n]
Michael Mack, MD,[o] Martin B. Leon, MD,[l] Vinod H. Thourani, MD,[p] John Carroll, MD,[q] Mitchell Krucoff, MD[b]

ABSTRACT

Transcatheter aortic valve replacement (TAVR) is the standard of care for severe, symptomatic aortic stenosis. Real-world TAVR data collection contributes to benefit/risk assessment and safety evidence for the U.S. Food and Drug Administration, quality evaluation for the Centers for Medicare and Medicaid Services and hospitals, as well as clinical research and real-world implementation through appropriate use criteria. The essential minimum core dataset for these purposes has not previously been defined but is necessary to promote efficient, reusable real-world data collection supporting quality, regulatory, and clinical applications. The authors performed a systematic review of the published research for high-impact TAVR studies and U.S. multicenter, multidevice registries. Two expert task forces, one from the Predictable and Sustainable Implementation of National Cardiovascular Registries/Heart Valve Collaboratory and another from The Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry convened separately and then met to reconcile a final list of essential data elements. From 276 unique data elements considered, unanimous consensus agreement was achieved on 132 "core" data elements, with the most common reasons for exclusion from the minimum core dataset being burden or difficulty in accurate assessment (36.9%), duplicative information (33.3%), and low likelihood of affecting outcomes (10.7%). After a systematic review and extensive discussions, a multilateral group of academicians, industry representatives, and regulators established 132 interoperable, reusable essential core data elements essential to supporting more efficient, consistent, and informative TAVR device evidence for regulatory submissions, safety surveillance, best practice, and hospital quality assessments. (J Am Coll Cardiol Intv 2022;15:685–697)
© 2022 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

**ABBREVIATIONS
AND ACRONYMS**

ACC = American College of
Cardiology

CMS = Centers for Medicare
and Medicaid Services

DCF = data collection form

EHR = electronic health record

FDA = U.S. Food and Drug
Administration

NCD = national coverage
determination

STS = The Society of Thoracic
Surgeons

TAVR = transcatheter aortic
valve replacement

Transcatheter aortic valve replacement (TAVR) is a transformative medical device technology that has revolutionized the care of aortic stenosis, and it has matured from a breakthrough technology to a broadly applicable standard of care. Regulatory approvals of TAVR by the U.S. Food and Drug Administration (FDA) and reimbursement provided by the Centers for Medicare and Medicaid Services (CMS) created significant interest in more efficient, higher quality real-world data collection to help fulfill postmarket surveillance and coverage with evidence development requirements. Additionally, TAVR was developed and approved in the context of a novel multidisciplinary heart team concept of clinical care. The combination of the initial clinical introduction of a novel, transformational medical device and a novel clinical pathway of care also suggested a need for hospital quality assessment and benchmarking. To create a uniquely comprehensive system of data collection to meet these needs as well as insight on novel developments and indications for use, The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), in collaboration with the FDA, CMS, and industry, hospital, and patient partners, combined to create the TVT (Transcatheter Valve Therapy) Registry, a groundbreaking multistakeholder registry.

However, as TAVR has matured from a breakthrough technology to a standard of care for severe, symptomatic, aortic stenosis,[1] the overlap in what real-world data are needed for clinical, quality, and regulatory evidence has evolved. Early studies of TAVR used more extensive case report forms than contemporary pivotal approval trials. The TVT Registry's efforts to include and balance the needs of stakeholders such as the FDA, CMS, industry, and professional societies have also focused on the imperative for contemporary efficiency in TAVR data collection on patients, procedures, and outcomes, which has become redundant and burdensome for clinical sites. Currently, sites collect nearly identical data for: 1) clinical documentation entered into electronic health records (EHR); 2) quality metrics to satisfy CMS national coverage determination (NCD) and coverage with evidence development requirements documentation entered into the TVT Registry[2,3]; and 3) case report forms in patients participating in prospective TAVR device studies.

To meet the needs of the evolving field of TAVR and lower data capture burdens while enhancing the
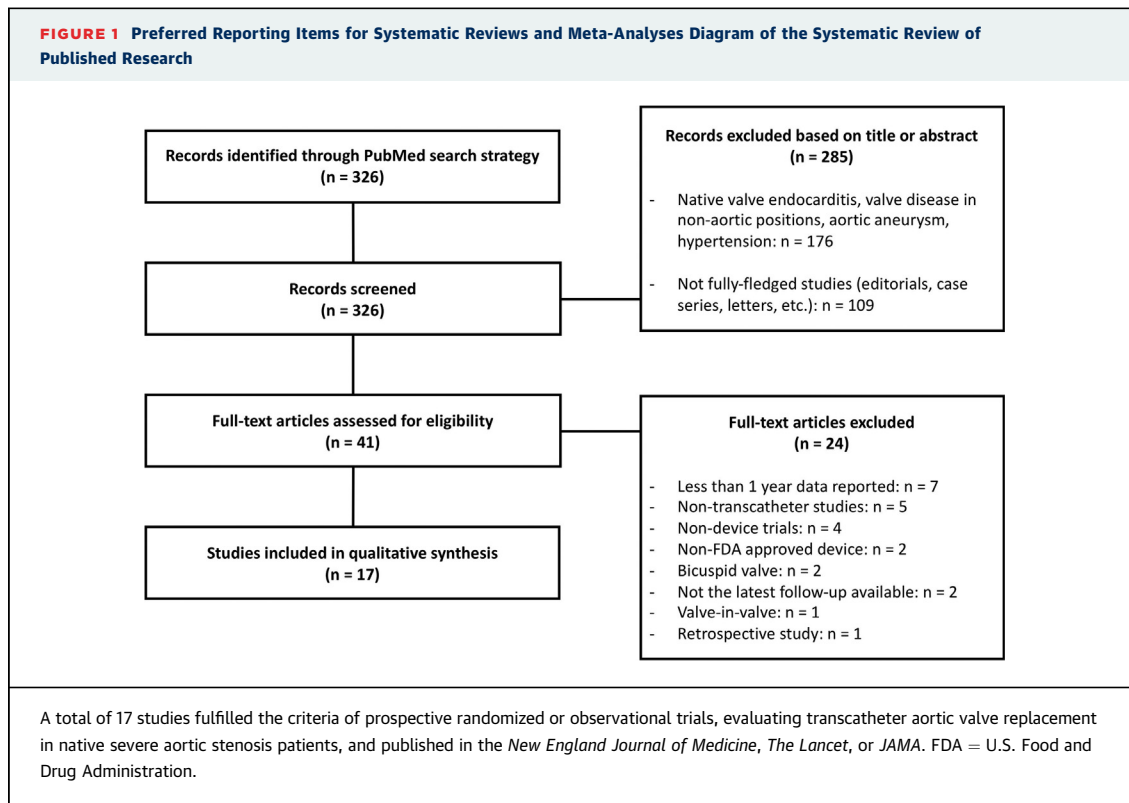
HIGHLIGHTS

- Core data elements to meet TAVR quality, regulatory, and clinical needs are lacking.

- A multilateral stakeholder group has established 132 core data elements.

- TAVR core data elements can reduce data burden while maintaining evidence generation.

quality of evidence applied to clinical trials, quality assessment, and regulatory decisions, a collaboration across the PASSION CV (Predictable and Sustainable Implementation of National Cardiovascular Registries) Lean Valve Data Collection Form Initiative, the HVC (Heart Valve Collaboratory) (a multidisciplinary collaboration among academic physicians, industry partners, and regulators), and the STS/ACC TVT Registry sought to: 1) define a basic aortic valve dataset by conducting a systematic research and data collection form (DCF) review that informed consensus identification of minimum core data elements; 2) implement the results of the consensus process into the TVT Registry; and 3) deliver a peer-reviewed document into the public domain delineating the process, the minimum core data elements comprising the basic (essential) dataset, and the data elements excluded from the basic dataset. This first report represents the completion of this process for TAVR.

METHODS

SYSTEMATIC RESEARCH REVIEW. A systematic review of the published research based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement[4] was undertaken to identify those data elements most frequently reported across scientific reports of TAVR procedures.

The following criteria were used to build the search strategy: 1) the population included patients with aortic stenosis; 2) the intervention studied was TAVR in native valves; 3) the control groups in randomized studies were surgical aortic valve replacement, TAVR with a different device, or medical management; 4) no specific outcomes were selected; and 5) studies included were randomized or well-conducted prospective observational studies, evaluating current FDA-approved devices, with a minimum of 1-year clinical follow-up, and published in the *New England Journal of Medicine*, *The Lancet*, or *JAMA*. When multiple follow-up studies of the same trial were

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses Diagram of the Systematic Review of Published Research

A total of 17 studies fulfilled the criteria of prospective randomized or observational trials, evaluating transcatheter aortic valve replacement in native severe aortic stenosis patients, and published in the *New England Journal of Medicine*, *The Lancet*, or *JAMA*. FDA = U.S. Food and Drug Administration.

available, both the original study and the most recent follow-up study were included. Results were limited to these 3 journals under the rationale that although they do not contain every informative study of TAVR, they do represent all of the pivotal device trials of TAVR and therefore reflect those variables necessary to meet the clinical and regulatory bar for establishing the efficacy and safety of TAVR devices.

The database used for the search was PubMed/MEDLINE, ranging from January 1, 2009, to September 1, 2020. The complete search strategy with specific terms used is available in the Supplemental Appendix. Three reviewers systematically identified titles in the database search, removed duplicates, screened abstracts, and confirmed eligibility through the evaluation of the full text (Supplemental Table 1). When there was disagreement, a fourth reviewer made the final decision to include or exclude the study. In addition, we included the TVT Registry DCF, as the TVT Registry contains more than 98% of TAVR sites in the United States,[5] incorporates the Valve Academic Research Consortium definitions, and has provided evidence for both quality and regulatory applications. ClinicalTrials.gov was searched to identify any additional observational clinical registries currently active in the United States, recruiting

TAVR patients, and device agnostic. The search strategy is available in the Supplemental Appendix.

SYNTHESIS OF DATA ELEMENTS. After study selection was completed, 3 reviewers meticulously searched, selected for, and harmonized data elements across all included studies. The collected data elements were reconciled and harmonized with the DCF of the STS/ACC TVT Registry version 3.0 for TAVR, the only active registry identified by our search (see "Results").

DETERMINATION OF MINIMUM CORE AND COMPREHENSIVE DATA ELEMENTS. A task force appointed by the Lean Aortic Valve DCF PASSION CV/HVC team, composed of academic researchers in structural heart disease institutionally supported by the Cardiovascular Research Foundation, the Baylor College of Medicine, the Duke Clinical Research Institute, industry representatives, and FDA staff members, reviewed all collected data elements and the number of appearances in published papers and DCFs. The TAVR data elements were grouped into 3 domains: baseline data (demographics and comorbidities, laboratory tests and imaging), procedural data, and follow-up data (outcomes, laboratory tests and imaging).

TABLE 1   Selected Studies

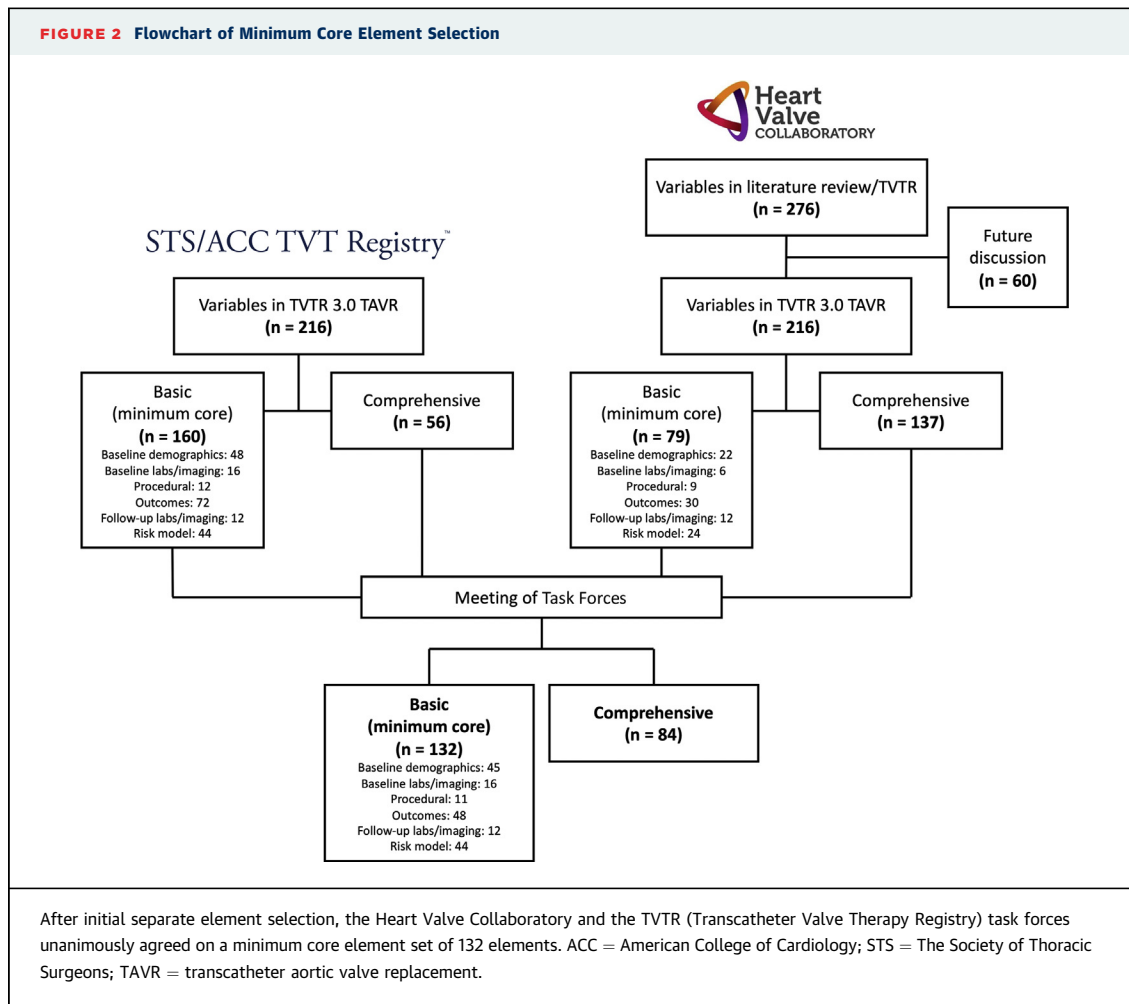| First Author	Title	Year	N	Population	Intervention	Device	Randomized	Timing
Leon et al[5]	PARTNER IB	2010	358	Inoperable severe aortic stenosis	TAVR vs medical therapy	SAPIEN	Yes	1 y
Smith et al[7]	PARTNER IA	2011	699	High-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN	Yes	1 y
Gilard et al[15]	FRANCE 2	2012	3,195	High-risk severe aortic stenosis	TAVR	SAPIEN, CoreValve	No	1 y
Adams et al[16]	U.S. CoreValve High Risk Study	2014	795	High-risk severe aortic stenosis	TAVR vs SAVR	CoreValve	Yes	1 y
Holmes et al[17]	TVT Registry	2015	12,182	Severe aortic stenosis	TAVR	Not specified	No	1 y
Kapadia et al[18]	PARTNER IB	2015	358	Inoperable severe aortic stenosis	TAVR vs medical therapy	SAPIEN	Yes	5 y
Mack et al[19]	PARTNER IA	2015	699	High-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN	Yes	5 y
Leon et al[20]	PARTNER IIA	2016	2,032	Intermediate-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN XT	Yes	1 y
Thourani et al[21]	SAPIEN 3 Intermediate Risk	2016	1,710	Intermediate-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN 3	No	1 y
Regueiro et al[22]	Infectious Endocarditis Registry	2016	250	Severe aortic stenosis	TAVR	SEV, BEV	No	2 y
Reardon et al[8]	SURTAVI	2017	1,746	Intermediate-risk severe aortic stenosis	TAVR vs SAVR	CoreValve, Evolut	Yes	2 y
Chakravarty et al[9]	RESOLVE and SAVORY registries	2017	931	Severe aortic stenosis	TAVR vs SAVR	Multiple	No	Mean follow-up of 540 d
Feldman et al[10]	REPRISE III	2018	912	Extreme or high-risk severe aortic stenosis	TAVR with MEV vs TAVR with SEV	Lotus	Yes	1 y
Inohara et al[11]	TVT RAS Inhibitor	2018	15,896	Severe aortic stenosis	TAVR	Not specified	No	1 y
Popma et al[12]	Low-Risk Evolut Trial	2019	1,468	Low-risk severe aortic stenosis	TAVR vs SAVR	Evolut	Yes	2 y
Mack et al[13]	PARTNER III	2019	1,000	Low-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN 3	Yes	1 y
Makkar et al[14]	PARTNER IIA	2020	2,032	Intermediate-risk severe aortic stenosis	TAVR vs SAVR	SAPIEN XT	Yes	5 y

FRANCE = French Aortic National CoreValve and Edwards; MEV = mechanically expandable valve; PARTNER = Placement of Aortic Transcatheter Valve; RAS = renin-angiotensin system; REPRISE III = Repositionable Percutaneous Replacement of Stenotic Aortic Valve Through Implantation of Lotus™ Valve System - Randomized Clinical Evaluation; RESOLVE = Assessment of Transcatheter and Surgical Aortic Bioprosthetic Valve Thrombosis and Its Treatment With Anticoagulation; SAVORY = Subclinical Aortic Valve Bioprosthesis Thrombosis Assessed With 4D CT; SAVR = surgical aortic valve replacement; SEV = self-expandable valve; SURTAVI = Surgical Replacement and Transcatheter Aortic Valve Implantation; TAVR = transcatheter aortic valve implantation; TVT = Transcatheter Valve Therapy.

The task force discussed individual data elements in weekly teleconferences, reaching consensus on whether to include each element as a "basic core dataset" (eg, essential minimum core) or "comprehensive dataset" (additional data elements pertinent to some, but not all, applications). Specifically, a data element was included in the proposed basic (essential minimum core) dataset only if a unanimous consensus of all committee members was reached on its importance to the stated clinical, quality, and regulatory applications. Conversely, unanimous consensus was also required for all data elements excluded from the basic core dataset. An independent team organized by the leadership of the STS/ACC TVT Registry, composed of TVT Registry steering committee members, academic leaders in structural heart disease, TVT Registry staff members, and members of the TVT Registry analytical center, but not from industry or from the FDA, performed a similar consensus evaluation of data elements. The full list of participants, affiliations, and functions is available in Supplemental Table 1. The final designations of "basic core dataset" and "comprehensive dataset" represent unanimous consensus between the 2 independent groups, and the rationale for rejection of data elements from either of these designations was recorded according to the definitions given in Supplemental Table 2.

RESULTS

SYSTEMATIC RESEARCH AND REGISTRY DCF REVIEW. A total of 326 studies were identified in the PubMed search (Figure 1). No duplicates were present, and all were screened on the basis of the title and

FIGURE 2   Flowchart of Minimum Core Element Selection

After initial separate element selection, the Heart Valve Collaboratory and the TVTR (Transcatheter Valve Therapy Registry) task forces unanimously agreed on a minimum core element set of 132 elements. ACC = American College of Cardiology; STS = The Society of Thoracic Surgeons; TAVR = transcatheter aortic valve replacement.

abstract for inclusion. Studies not relevant to the topic (n = 176) and papers that did not consist of original research (n = 109) were excluded. A total of 41 full-text papers were evaluated for eligibility. Of these, a total of 17 studies fulfilled the inclusion criteria and were selected for qualitative analysis.[6-22] Selected studies are described in **Table 1**. In terms of registries, 5 entries were identified in our Clinical-Trials.gov search. Only the TVT Registry fulfilled the criteria of an ongoing, prospective, device-agnostic, national registry in the United States.

ELEMENT FREQUENCY AND SELECTION. A total of 276 data elements were identified in the aortic research review and TVT Registry 3.0 form, appearing 1,054 times in the papers and DCFs (Supplemental Table 3). Among the 276 data elements, 216 are present in the TVT Registry 3.0 form (57 baseline demographics and comorbidities, 35 baseline laboratory tests and imaging, 25 procedural, 79 follow-up outcomes, and 20 follow-up laboratory tests and

imaging). The majority (74.6%) appeared <5 times in our search, with only 4.0% of data elements appearing 15 or more times.

MEETING OF PASSION CV/HVC AND TVT REGISTRY TASK FORCES. The Lean Aortic DCF PASSION CV/HVC task force initially considered 79 of the identified data elements as basic (minimum core) (22 baseline demographics and comorbidities, 6 baseline laboratory tests and imaging, 9 procedural, 30 follow-up outcomes, and 12 follow-up laboratory tests and imaging; 24 part of the risk model), and the TVT Registry task force considered 160 as basic (minimum core) dataset elements (48 baseline demographics and comorbidities, 16 baseline laboratory tests and imaging, 12 procedural, 72 follow-up outcomes, and 12 follow-up laboratory tests and imaging; 44 of these variables constituted the complete risk model) (**Figure 2**). Among the 160 data elements selected as basic (minimum core) by TVT Registry, the Lean Aortic DCF PASSION CV/HVC task force initially

TABLE 2   Core Variables: Baseline

	Category	Number of Appearances in Literature/TVT Registry
Age[a]	Baseline, demographics, and comorbidities	18
Sex[a]	Baseline, demographics, and comorbidities	18
STS score/surgical risk	Baseline, demographics, and comorbidities	15
NYHA functional class[a]	Baseline, demographics, and comorbidities	15
Race/ethnicity[a]	Baseline, demographics, and comorbidities	4
Height[a]	Baseline, demographics, and comorbidities	1
Weight[a]	Baseline, demographics, and comorbidities	1
Previous stroke[a]	Baseline, demographics, and comorbidities	15
Peripheral arterial disease[a]	Baseline, demographics, and comorbidities	14
Diabetes mellitus[a]	Baseline, demographics, and comorbidities	10
Home oxygen use[a]	Baseline, demographics, and comorbidities	9
Congestive heart failure	Baseline, demographics, and comorbidities	4
Cardiogenic shock	Baseline, demographics, and comorbidities	1
Symptoms of aortic stenosis present	Baseline, demographics, and comorbidities	1
Chest wall deformity/hostile chest[a]	Baseline, demographics, and comorbidities	6
Extensively calcified aorta/ porcelain aorta[a]	Baseline, demographics, and comorbidities	5
Dialysis[a]	Baseline, demographics, and comorbidities	4
Carotid artery stenosis[a]	Baseline, demographics, and comorbidities	2
Chronic lung disease[a]	Baseline, demographics, and comorbidities	2
Endocarditis[a]	Baseline, demographics, and comorbidities	2
Smoker[a]	Baseline, demographics, and comorbidities	1
Previous myocardial infarction[a]	Baseline, demographics, and comorbidities	13
Previous CABG[a]	Baseline, demographics, and comorbidities	13
Previous PCI[a]	Baseline, demographics, and comorbidities	11
Atrial fibrillation/atrial flutter[a]	Baseline, demographics, and comorbidities	15
Permanent pacemaker[a]	Baseline, demographics, and comorbidities	14
Implantable cardioverter defibrillator[a]	Baseline, demographics, and comorbidities	3
Previous SAVR	Baseline, demographics, and comorbidities	3
Previous TAVR	Baseline, demographics, and comorbidities	1
Previous BAV	Baseline, demographics, and comorbidities	6
Previous aortic valve procedure[a]	Baseline, demographics, and comorbidities	2
Number or prior open heart cardiac procedures[a]	Baseline, demographics, and comorbidities	2
Previous valve surgery[a]	Baseline, demographics, and comorbidities	2
Previous aortic valve repair surgery	Baseline, demographics, and comorbidities	1
Aortic valve transcatheter intervention	Baseline, demographics, and comorbidities	1
Mitral valve procedure	Baseline, demographics, and comorbidities	1
Mitral valve annuloplasty ring surgery	Baseline, demographics, and comorbidities	1
Mitral valve repair surgery	Baseline, demographics, and comorbidities	1
Mitral valve replacement surgery	Baseline, demographics, and comorbidities	1
Mitral valve transcatheter intervention	Baseline, demographics, and comorbidities	1
Pulmonic valve procedure	Baseline, demographics, and comorbidities	1
Tricuspid valve procedure	Baseline, demographics, and comorbidities	1
KCCQ score[a]	Baseline, demographics, and comorbidities	6

Continued on the next page

agreed on 72. Among the 56 data elements selected as comprehensive by TVT Registry, the Lean Aortic DCF PASSION CV/HVC task force considered 7 as basic (minimum core). After discussion with involved stakeholders of both task forces, there was unanimous agreement to select 132 data elements as basic (minimum core: 45 baseline demographics and comorbidities, 16 baseline laboratory tests and imaging, 11 procedural, 48 follow-up outcomes, and 12 follow-up laboratory tests and imaging) (**Tables 2 to 4**) and to maintain 84 data elements as comprehensive (Supplemental Tables 4 to 6). All 44 variables of the risk model were included in the final core data elements.

Several reasons were cited by the Lean Aortic DCF PASSION CV/HVC and TVT Registry task forces to exclude certain data elements from the basic (minimum core) dataset designation. The most common reasons were that the element was believed to be challenging to assess accurately (36.9%), that the element is captured in duplicate (33.3%), or that the element is unlikely to affect clinical outcomes (10.7%). **Figure 3** summarizes these reasons. The full list of data elements and justifications is available in a spreadsheet in the Supplemental Appendix.

IMPLEMENTATION OF CONSENSUS BASIC (MINIMUM CORE) DATA ELEMENTS INTO THE TVT REGISTRY.
All 132 of the basic (minimum core) data elements were implemented and were designated the "required" basic dataset within the TVT Registry as of January 2021. Because some of the variables designated as "basic" were programmatically linked to variables not designated as basic, an additional 35 variables were kept in the "required" TVT Registry 3.0 dataset to ensure retention of all of the basic (minimum core) data elements.

DISCUSSION

Current data needs in TAVR include fulfilling clinical, quality, and regulatory evidence and reporting expectations, frequently through burdensome, redundant, heterogenous work flow pathways that undermine data integrity (missingness, accuracy), add costs, and delay aggregation of evidence. Recognizing the substantial content overlap across these independent applications, the establishment of a minimum core dataset essential to all of these needs promotes substantial enhancement of consistency, efficiency, and quality of TAVR evidence overall. This critical landscape change thus provides a platform to remove the current redundant "re-re-entry" of procedural and clinical data across clinical EHRs, quality

registries, and clinical trial DCFs while enhancing consistency, quality, and efficiency to TAVR evidence accrual across clinical, quality, and regulatory benefit/risk and safety characterizations. Although basic (minimum core) datasets are not necessarily sufficient for any of these applications, the fact that they are essential to all of them provides an unique opportunity to enable efficiencies that enhance the informative content of any regulatory, quality, or clinical evidence derived through this construct.

Through the conduct of a systematic review and reconciliation across 2 independent consensus processes, we present the first comprehensive effort to produce a consensus list of "basic" (minimum core) data elements in contemporary TAVR. The 132 basic (minimum core) data elements represent 61% of the 216 data elements in the TVT Registry (Central Illustration). In terms of categories, the consensus basic (minimum core) data elements represent 79% of original baseline demographics and comorbidities, 46% of the baseline laboratory tests and imaging, 44% of the procedural elements, 61% of follow-up outcomes, and 60% of follow-up laboratory tests and imaging. Although these "basic" (essential minimum core) data elements were derived through a consensus process designed to address U.S. regulatory expectations and hospital quality requirements, the majority of these data elements, with the exception of U.S.-based demographic definitions, are likely applicable to and already widely used in international data collection as well.

TAVR is an established procedure with an extensive list of randomized clinical trials supporting its use performed over the course of a decade.[6-8,12,13,16,18,19,20] Over this time, TAVR devices have undergone multiple generational improvements and device designs, as well as flattening of the volume-outcomes and learning curves.[23,24] As a result of the technological maturity and the advanced dispersion of TAVR in the United States, data elements necessary to fulfill FDA benefit/risk assessment or safety surveillance and real-world quality assessment requirements have become more focused. In light of this, for example, elements related to device identification, which may be useful for the evaluation of long-term outcomes, were preserved as basic (minimum core). In addition, we have attempted to retain elements that were outlined in the most recent CMS TAVR NCD as necessary for building a quality assessment composite.[25] Certain elements essential for quality evaluation by distinct levels (ie, patient, practitioner, and facility level) were also kept. We have also included in the basic (minimum core) dataset set the majority of

baseline demographic and comorbidity elements (79%). This is important given the NCD requirement to identify the factors that predict the quality metric.[25] Finally, as another recently added priority of the

TABLE 2 Continued		
	Category	Number of Appearances in Literature/TVT Registry
Gait speed, walking 5 m[a]	Baseline, demographics, and comorbidities	10
Positive inotrope preprocedure[a]	Baseline, demographics, and comorbidities	1
Left main coronary artery disease[a]	Baseline, laboratory tests, and imaging	2
Proximal LAD ≥70%[a]	Baseline, laboratory tests, and imaging	1
Conduction defect[a]	Baseline, laboratory tests, and imaging	1
Creatinine[a]	Baseline, laboratory tests, and imaging	6
Hemoglobin[a]	Baseline, laboratory tests, and imaging	2
Platelet count[a]	Baseline, laboratory tests, and imaging	1
Baseline mean aortic valve gradient	Baseline, laboratory tests, and imaging	13
Baseline LVEF[a]	Baseline, laboratory tests, and imaging	12
Baseline aortic valve area	Baseline, laboratory tests, and imaging	11
Bicuspid aortic valve[a]	Baseline, laboratory tests, and imaging	1
Baseline aortic regurgitation[a]	Baseline, laboratory tests, and imaging	2
Baseline mitral regurgitation[a]	Baseline, laboratory tests, and imaging	2
Aortic valve disease etiology	Baseline, laboratory tests, and imaging	1
Aortic stenosis	Baseline, laboratory tests, and imaging	1
Baseline mitral valve mean gradient	Baseline, laboratory tests, and imaging	1
Baseline tricuspid regurgitation[a]	Baseline, laboratory tests, and imaging	1

[a]Risk model variables.

BAV = bicuspid aortic valve; CABG = coronary artery bypass graft; KCCQ = Kansas City Cardiomyopathy Questionnaire; LAD = left anterior descending coronary artery; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STS = The Society of Thoracic Surgeons; other abbreviations as in Table 1.

TABLE 3 Core Variables: Procedural		
	Category	Number of Appearances in Literature/TVT Registry
Procedure date[a]	Procedural	18
Type of valve	Procedural	15
Access type (transfemoral vs apical, etc)[a]	Procedural	10
Concomitant procedure	Procedural	3
Anesthesia type	Procedural	2
Dominant indication for procedure (AS vs AR)	Procedural	1
Procedure status (emergent/salvage/CPR)[a]	Procedural	1
Embolic protection	Procedural	1
Shock during procedure[a]	Procedural	1
Bioprosthetic valve fracture	Procedural	1
Operator name	Procedural	1

[a]Risk model variables.

AR = aortic regurgitation; AS = aortic stenosis; CPR = cardiopulmonary resuscitation; TVT = Transcatheter Valve Therapy.

TABLE 4 Core Variables: Follow-Up		
	Category	Number of Appearances in Literature/TVT Registry
Converted procedure to surgery	Outcomes, immediate/perioperative	7
Aborted procedure	Outcomes, immediate/perioperative	5
Multiple valves (≥2 implanted)	Outcomes, immediate/perioperative	6
Multiple valves because of valve embolization	Outcomes, immediate/perioperative	5
Cardiac perforation	Outcomes, immediate/perioperative	4
Stroke, ischemic	Outcomes, immediate/perioperative	4
Annular rupture	Outcomes, immediate/perioperative	2
Dialysis (new requirement)	Outcomes, immediate/perioperative	2
Access-site complications	Outcomes, immediate/perioperative	1
Atrial fibrillation	Outcomes, immediate/perioperative	1
Cardiac arrest	Outcomes, immediate/perioperative	1
Bailout/unplanned PCI	Outcomes, immediate/perioperative	1
Permanent pacemaker	Outcomes, immediate/perioperative	1
Reintervention, aortic valve	Outcomes, immediate/perioperative	1
Stroke, hemorrhagic	Outcomes, immediate/perioperative	3
Stroke, undetermined	Outcomes, immediate/perioperative	3
Bleeding, genitourinary	Outcomes, immediate/perioperative	1
Bleeding, other	Outcomes, immediate/perioperative	1
Bleeding, gastrointestinal	Outcomes, immediate/perioperative	1
Coronary artery compression	Outcomes, immediate/perioperative	1
Transfusion and number of transfusions	Outcomes, immediate/perioperative	2
Anticoagulation	Outcomes, immediate/perioperative	1
Discharge location	Outcomes, immediate/perioperative	3
Discharge, date/death	Outcomes, immediate/perioperative	3
Hospice care	Outcomes, immediate/perioperative	2
Cardiac rehabilitation referral	Outcomes, immediate/perioperative	2
Death	Outcomes, 1 mo/1 y	18
All stroke	Outcomes, 1 mo/1 y	15
New pacemaker/ICD	Outcomes, 1 mo/1 y	14
Repeat hospitalization	Outcomes, 1 mo/1 y	13
NYHA functional class	Outcomes, 1 mo/1 y	13
Major vascular complication	Outcomes, 1 mo/1 y	12
Aortic valve reintervention	Outcomes, 1 mo/1 y	12
Major bleeding	Outcomes, 1 mo/1 y	11
Endocarditis	Outcomes, 1 mo/1 y	11
New-onset atrial fibrillation	Outcomes, 1 mo/1 y	11
Acute kidney injury	Outcomes, 1 mo/1 y	11
KCCQ score	Outcomes, 1 mo/1 y	6
Cardiac surgery or intervention, other unplanned	Outcomes, 1 mo/1 y	1
Life-threatening/disabling bleeding	Outcomes, 1 mo/1 y	9
Renal replacement therapy	Outcomes, 1 mo/1 y	4
Stroke, ischemic	Outcomes, 1 mo/1 y	3
Stroke, hemorrhagic	Outcomes, 1 mo/1 y	1
Stroke, undetermined	Outcomes, 1 mo/1 y	1
Hospitalization for heart failure	Outcomes, 1 mo/1 y	6

Continued on the next page

NCD is the evaluation of long-term outcomes and durability, elements such as reintervention and valve thrombosis were selected as basic (minimum core).

Concurrently, when selecting elements for inclusion, the task forces prioritized those that were straightforward in their assessment and attempted to exclude variables requiring further adjudication from the basic (minimum core) dataset. For instance, the "stroke" data element will now be defined as a composite of all types of strokes, notwithstanding whether it was reported as hemorrhagic, ischemic, or unknown, because of the need for adjudication to reliably differentiate stroke subtypes. Importantly, the task forces agreed to preserve elements that indicate the clinical severity of an event, including the presence of neurologic sequelae. Other elements that may be too convoluted, such as neuroimaging or autopsy results, were not selected for the basic (minimum core) dataset. Thus, for selected applications or clinical trials of novel device designs, adding a module including core laboratory or independent adjudication processes and data elements might constitute a critical "module" to add to the core basic dataset to make a body of evidence more comprehensive and "fit to purpose." In summary, the continued and pragmatic assessment of benefit/risk and safety in TAVR procedures was the fundamental priority guiding the selection of the basic (minimum core) dataset. Establishment of the basic (minimum core) dataset is complementary to the variable definitions established by the Valve Academic Research Consortium, and together the 2 efforts help enhance consistency in approach and concepts across the data landscape for TAVR.

As a result of these fundamental guiding principles, data elements that are important for other purposes, such as appropriate use criteria, were also not included in this version of the basic (minimum core) dataset. Although appropriate use represents an important concept in the selection and provision of care, it is distinct (though complementary) to the assessment and improvement of quality of care. Additionally, with the rapid expansion of TAVR into all patient risk categories, existing appropriateness criteria may need to be revised to be clinically relevant.[1,26] For instance, data elements such as SYNTAX (SYNTA×) score and life expectancy <1 year, which are resource intensive to obtain and were originally embedded within TVT Registry to address issues of appropriate use, were not included in the basic (minimum core) dataset.[26] Specifically, SYNTAX score requires significant experience in its calculation and

is unlikely to be reliably obtained without core laboratory adjudication. In addition, physician-estimated life expectancy is notoriously imprecise.[27] Thus, although the basic (minimum core) data construct well supports evidence collections relevant to best practice guidelines, these basic (minimum core) data elements alone are not likely sufficient.

Another issue that the task forces frequently faced when evaluating data elements were those that are collected without methodologic consistency. An example is the data elements related to pulmonary disease. In TVT Registry 3.0, this comorbidity is collected in a specific element evaluating severity of chronic lung disease, in other data elements evaluating forced expiratory volume in 1 second and diffusing capacity for carbon monoxide, and finally in a home oxygen need element. Notwithstanding the difficulty in obtaining the data for some of these data elements, there may be little additional benefit, but consequential additional resource use, in obtaining essentially the same information in multiple ways. In alignment with the Academic Research Consortium emphasis, data elements in the basic (minimum core) dataset are intended to add value by adding consistency across clinical, quality, and regulatory evidence applications.

Given the CMS TAVR NCD requirements of quality assessment, the TVT Registry has devised and validated the TVT Registry Composite Risk Model,[28] which is extensively used to evaluate site performance. As such, to maintain compliance with this requirement and to foster collection of the minimum data elements needed for adequate hospital quality assessment, both task forces agreed to preserve within the basic (minimum core) dataset all 44 data elements needed to compute TVT Registry hospital quality assessment metrics. This decision accepted that some of the elements included by the current model may be less pertinent to state-of-the-art TAVR procedures and takes into account that the public acceptance of a risk model is dependent on achievement of technically adequate risk adjustment that is perceived to be comprehensive. For instance, data elements such as hostile chest and porcelain aorta are historical remnants of early TAVR and were reported in our search of the published research only in trials of first-generation devices,[6,7] in the trial of a device no longer available in the market,[10] and in early registry data.[15,17] However, these data elements were originally selected through consensus by a group of experts in risk modeling to ensure adequate and comprehensive risk adjustment with face validity. Importantly, existing TVT Registry TAVR risk models have full endorsement of the National Quality Forum.
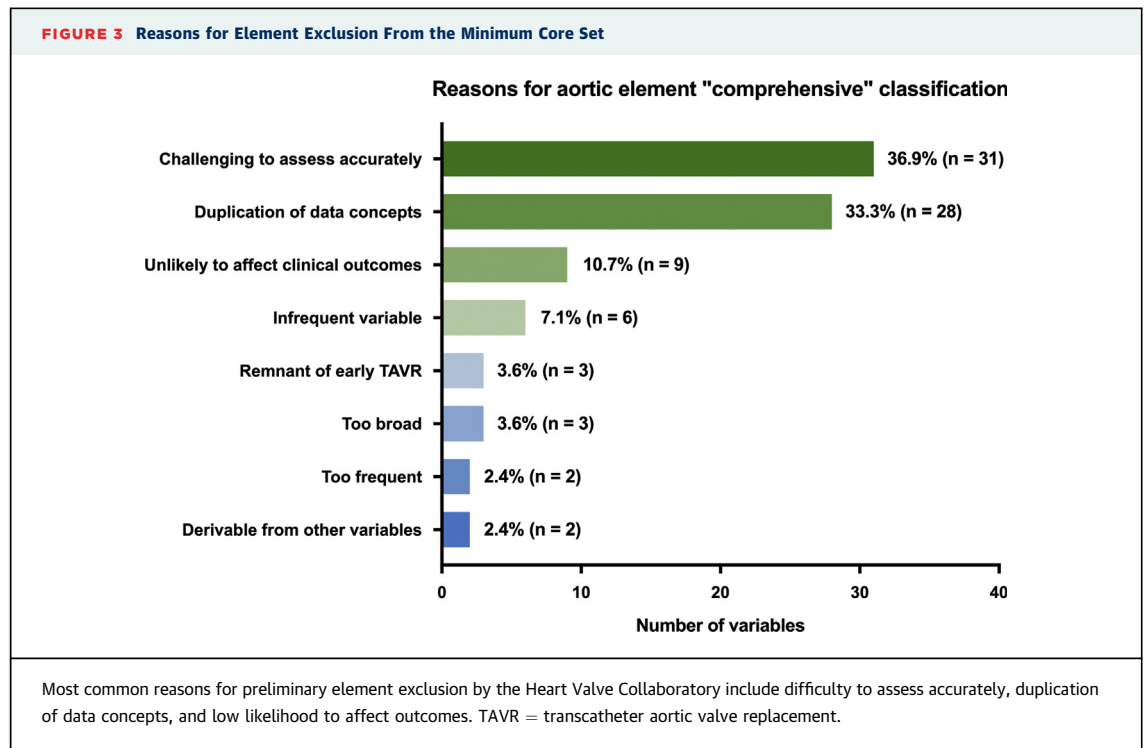
TABLE 4 Continued		
	Category	Number of Appearances in Literature/TVT Registry
Device thrombosis	Outcomes, 1 mo/1 y	3
Vascular surgery or intervention, unplanned	Outcomes, 1 mo/1 y	1
ICD	Outcomes, 1 mo/1 y	1
Creatinine	Follow-up, laboratory tests and imaging	1
Hemoglobin	Follow-up, laboratory tests and imaging	1
Aortic regurgitation	Follow-up, laboratory tests and imaging	2
Mean aortic valve gradient	Follow-up, laboratory tests and imaging	2
Paravalvular vs central AR	Follow-up, laboratory tests and imaging	1
Mean aortic valve gradient	Follow-up, laboratory tests and imaging	14
LVEF	Follow-up, laboratory tests and imaging	3
Aortic regurgitation	Follow-up, laboratory tests and imaging	3
Date	Follow-up, laboratory tests and imaging	1
Paravalvular AR	Follow-up, laboratory tests and imaging	13
Valve thrombosis	Follow-up, laboratory tests and imaging	5
Leaflet dysfunction	Follow-up, laboratory tests and imaging	3

ICD = implantable cardioverter-defibrillator; other abbreviations as in **Tables 1 to 3**.

Future iterations of the risk model and of the DCF may allow a reevaluation of the basic (minimum core) dataset status of these elements through expert consensus.

Importantly, the goal of the "lean" process undertaken was to establish, through consensus across stakeholders, the minimum data elements essential for the purposes of clinical best practice, quality, and/or benefit/risk and safety assessments. By definition, this also means that to create sufficient and fit-for-purpose data for any specific clinical, quality, or regulatory application per se, the basic (minimum core) dataset may need to be augmented with additional modules. Additionally, we note that the size and scope of any basic (minimum core) dataset mirrors the maturity of the field it serves. The present work reflects an evolution of the original FDA, CMS, and professional society efforts to construct an appropriately wide dataset for TAVR as a "breakthrough" technology to an updated version matching the interim increase in knowledge and development of quality initiatives as the provision of TAVR care in the United States has matured from a clinical discovery phase to an implementation phase.[29] Certainly, as the field of TAVR continues to evolve in the future, further adjustments to the basic (minimum core) dataset will likely again become necessary.

Finally, we also describe the real-world implementation of the basic (minimum core) dataset into

FIGURE 3 Reasons for Element Exclusion From the Minimum Core Set

Most common reasons for preliminary element exclusion by the Heart Valve Collaboratory include difficulty to assess accurately, duplication of data concepts, and low likelihood to affect outcomes. TAVR = transcatheter aortic valve replacement.
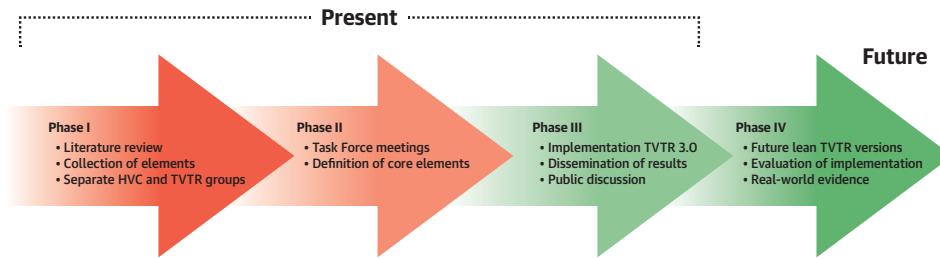
TVT Registry 3.0 and the process to reach these data elements is made public through this paper. Future efforts within the TVT Registry will include prospective plans to evaluate the implementation of the minimum core dataset as a factor in enhanced data quality within the TVT Registry or as a basis for further refinement of the mandatory TVT Registry data elements. Future efforts across clinicians, the FDA, and industry may include leveraging the basic (minimum core) data infrastructure for better, more efficient, and prospective registry-based TAVR device evaluations or safety assessments. Furthermore, in sharing both these processes and the principles of minimum core data element structure, future efforts to develop minimum core data infrastructure for other devices may be facilitated by "use/reuse" of the "basic recipe."

Developing a basic (minimum core) dataset within structural heart disease has the potential to facilitate future innovations ranging from automatic data collection[30] to registry-based trials[31,32] and profound international collaboration.[33] Importantly, integration of the minimum core data elements within the broader TVT Registry DCF will speed the instantiation of these basic (minimum core) data elements within data collection and health informatics systems through the TVT Registry's national mandate and reach. The integration of these basic data elements into ongoing health informatics efforts to develop semiautomated and automated data extraction from EHRs will be a key future step necessary to realize the full gains in efficiency and data quality associated with the "lean" data element concept.
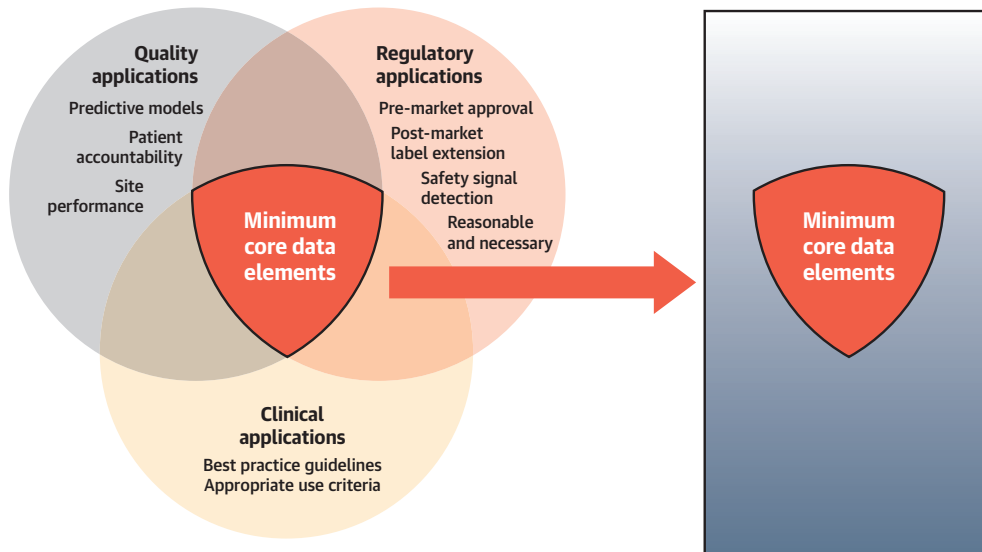
Finally, an operational benefit that can be obtained from the creation of a basic (minimum core) dataset is in the reduction of data burden. There is a substantial unreimbursed cost[34] involved in participation in a national registry, especially until ongoing efforts by professional societies, EHR vendors, and electronic interoperability standards groups result in automated or semiautomated extraction of relevant data from structured or unstructured EMRs. Therefore, the designation of "basic" (minimum core) and "comprehensive" data elements allow participating centers to choose and manage the level of resource use necessary to complete data collection. Although extraction of the basic (minimum core) data elements will provide the foundations for more efficient and adequate prospective benefit/risk studies and safety surveillance and for hospital quality assessment, extraction and submission of the comprehensive data elements permit assessment of appropriate use and even potential improvements in hospital quality, as exemplified by regional and other quality collaboratives.[35,36]

CENTRAL ILLUSTRATION Minimum Core Data Elements in Transcatheter Aortic Valvular Interventions and Instantiation of the Minimum Core Data Elements in the Transcatheter Valve Therapy Registry

Simonato M, et al. J Am Coll Cardiol Intv. 2022;15(7):685–697.

The Heart Valve Collaboratory and TVT (Transcatheter Valve Therapy) Registry task. Registry task forces unanimously selected 132 minimum core data elements for transcatheter aortic valve replacement procedures, on the basis of an extensive systematic review of the published research and discussions involving key experts and leaders in the field. ACC = American College of Cardiology; KCCQ = Kansas City Cardiomyopathy Questionnaire; STS = The Society of Thoracic Surgeons; TVT = transcatheter valve therapy.

CONCLUSIONS

After a systematic review and extensive discussions, the collaborative partnership between the Lean Aortic DCF PASSION CV/HVC task force and the TVT Registry was able to establish 132 "basic" minimum core data elements essential to clinical, regulatory, and hospital quality assessment. These elements represent the minimum dataset targeted to fulfill FDA and CMS reporting requirements for TAVR, and collection of additional elements may be needed to provide sufficient fit-for-purpose evidence to establish extended insights within the total device lifecycle. Establishment of the "basic" (minimum core) data elements in the public domain support the efficiency, speed, and predictability of future TAVR device evidence collections and concomitantly reduce the burden on hospitals. Furthermore, these processes and principles of core data element's structure can facilitate similar approaches for other structural heart devices, cardiovascular devices, and medical devices in general.

ADDRESS FOR CORRESPONDENCE: Dr Sreekanth Vemulapalli, Duke Clinical Research Institute, Box 3126, Durham, North Carolina 27710, USA. E-mail: sreekanth.vemulapalli@duke.edu.

REFERENCES

1. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease. *J Am Coll Cardiol*. 2021;77:e25-e197.

2. U.S. Food and Drug Administration. Premarket approval (PMA)—Edwards SAPIEN. Accessed February 9, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100041

3. Centers for Medicare and Medicaid Services. Decision memo for transcatheter aortic valve replacement (TAVR) (CAG-00430N). Accessed February 9, 2021. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257

4. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ*. 2009;339:332-336.

5. Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of transcatheter aortic valve replacement. *J Am Coll Cardiol*. 2020;76:2492-2516.

6. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med*. 2010;363:1597-1607.

7. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *N Engl J Med*. 2011;364:2187-2198.

8. Reardon MJ, Van Mieghem NM, Popma JJ, et al. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2017;376:1321-1331.

9. Chakravarty T, Søndergaard L, Friedman J, et al. Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study. *Lancet*. 2017;389:2383-2392.

10. Feldman TE, Reardon MJ, Rajagopal V, et al. Effect of mechanically expanded vs self-expanding transcatheter aortic valve replacement on mortality and major adverse clinical events in high-risk patients with aortic stenosis the REPRISE III randomized clinical trial. *JAMA*. 2018;319:27-37.

11. Inohara T, Manandhar P, Kosinski AS, et al. Association of renin-angiotensin inhibitor treatment with mortality and heart failure readmission in patients with transcatheter aortic valve replacement. *JAMA*. 2018;320:2231-2240.

12. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med*. 2019;380:1706-1715.

13. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med*. 2019;380:1695-1705.

14. Makkar RR, Thourani VH, Mack MJ, et al. Five-year outcomes of transcatheter or surgical aortic-valve replacement. *N Engl J Med*. 2020;382:799-809.

15. Gilard M, Eltchaninoff H, Iung B, et al. Registry of transcatheter aortic-valve implantation in high-risk patients. *N Engl J Med*. 2012;366:1705-1715.

16. Adams DH, Popma JJ, Reardon MJ, et al. Transcatheter aortic-valve replacement with a self-expanding prosthesis. *N Engl J Med*. 2014;370:1790-1798.

17. Holmes DR, Brennan JM, Rumsfeld JS, et al. Clinical outcomes at 1 year following transcatheter aortic valve replacement. *JAMA*. 2015;313:1019-1028.

18. Kapadia SR, Leon MB, Makkar RR, et al. 5-Year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385:2485-2491.

19. Mack MJ, Leon MB, Smith CR, et al. 5-Year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385:2477-2484.

20. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med*. 2016;374:1609-1620.

21. Thourani VH, Kodali S, Makkar RR, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. *Lancet*. 2016;387:2218-2225.

22. Regueiro A, Linke A, Latib A, et al. Association between transcatheter aortic valve replacement and subsequent infective endocarditis and in-hospital death. *JAMA*. 2016;316:1083-1092.

23. Carroll JD, Vemulapalli S, Dai D, et al. Procedural experience for transcatheter aortic valve replacement and relation to outcomes: the STS/ACC TVT Registry. *J Am Coll Cardiol*. 2017;70:29-41.

24. Vemulapalli S, Carroll JD, Mack MJ, et al. Procedural volume and outcomes for transcatheter aortic-valve replacement. *N Engl J Med*. 2019;380:2541-2550.

25. Centers for Medicare and Medicaid Services. National coverage determination (NCD) for transcatheter aortic valve replacement (TAVR) (20.32).

Accessed February 9, 2021. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDid=355

26. Bonow RO, Brown AS, Gillam LD, et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 appropriate use criteria for the treatment of patients with severe aortic stenosis. *J Am Coll Cardiol.* 2017;70:2566–2598.

27. Buchan TA, Ross HJ, McDonald M, et al. Physician judgement vs model-predicted prognosis in patients with heart failure. *Can J Cardiol.* 2020;36:84–91.

28. Desai ND, O'Brien SM, Cohen DJ, et al. A composite metric for benchmarking site performance in TAVR: results from the STS/ACC TVT Registry. *Circulation.* 2021;144:186–194.

29. Vemulapalli S, Thourani VH. Aortic valve replacement and patient-centered implementation. *J Am Coll Cardiol.* 2021;78:2173–2176.

30. Hess CN, Rao SV, Kong DF, et al. Embedding a randomized clinical trial into an ongoing registry infrastructure: unique opportunities for efficiency in design of the Study of Access Site for Enhancement of Percutaneous Coronary Intervention for Women (SAFE-PCI for Women). *Am Heart J.* 2013;166:421–428.

31. Fröbert O, Lagerqvist B, Olivecrona GK, et al. Thrombus aspiration during ST-segment elevation myocardial infarction. *N Engl J Med.* 2013;369:1587–1597.

32. Lauer MS, D'Agostino RB. The randomized registry trial—the next disruptive technology in clinical research? *N Engl J Med.* 2013;369:1579–1581.

33. Uchida T, Ikeno F, Ikeda K, et al. Global cardiovascular device innovation: Japan-USA synergies—Harmonization by Doing (HBD) program, a consortium of regulatory agencies, medical device industry, and academic institutions. *Circ J.* 2013;77:1714–1718.

34. Cadet JV. Clinical registries: getting necessary & costly. Cardiovascular Business. Accessed January 14, 2021. https://www.cardiovascularbusiness.com/topics/practice-management/clinical-registries-getting-necessary-costly

35. Likosky DS, Harrington SD, Cabrera L, et al. Collaborative quality improvement reduces postoperative pneumonia after isolated coronary artery bypass grafting surgery. *Circ Cardiovasc Qual Outcomes.* 2018;11:e004756.

36. Bradley SM, Adusumalli S, Amin AP, et al. The Cardiovascular Quality Improvement and Care Innovation Consortium. *Circ Cardiovasc Qual Outcomes.* 2021;14:e006753.

KEY WORDS transcatheter aortic valve replacement

APPENDIX For supplemental methods, references, and tables, as well as a description of the search strategy, please see the online version of this paper.

Go to http://www.acc.org/jacc-journals-cme to take the CME/MOC/ECME quiz for this article.