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THE CANADIAN CARDIOVASCULAR SOCIETY QUALITY INDICATORS E-CATALOGUE

QUALITY INDICATORS FOR TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

A CCS CONSENSUS DOCUMENT

FINAL V2

Last updated: April 2019

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BACKGROUND

The quality indicators outlined in this document have been selected through a national consensus process as the key quality indicators specific to **Transcatheter Aortic Valve Implantation (TAVI).**

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STRUCTURAL INDICATORS

HEART TEAM TREATMENT RECOMMENDATION	
Description	Documented consensus treatment recommendation made by Heart Team at multidisciplinary meeting to review patients. The Heart Team should meet minimum requirements of an interventional cardiologist and cardiac surgeon but should ideally be composed of the patient's treating physician, geriatrician or internist, cardiac imaging specialist and Transcatheter Aortic Valve Implantation (TAVI) nurse coordinator. This multi-disciplinary team should convene as a group on a regular basis to review and interpret clinical data to arrive at a consensus on the optimal treatment strategy for each patient.
Numerator	Number of TAVI patients who have a documented treatment recommendation from a heart team (minimum of interventional cardiologist and cardiac surgeon) meeting at a center during the given observation period.
Denominator	Total number of patients referred for TAVI at a center in a given observation period.
Method of Calculation	This structure indicator would be confirmed annually by the participating sites (i.e., Does a multidisciplinary team that includes at minimum a cardiologist and cardiac surgeon meet regularly to discuss a consensus treatment recommendations for patients referred for TAVI?)
Sources of Data	Institutional clinical data Hospital records (patient charts)

Rationale

Valve Academic Research Consortium-2 recommends the use of a heart team for patient evaluation. Such an approach allows for the adjustment of the decision-making process according to local experience and circumstances. The most important role of the heart team is to provide customized management decisions for common and unusual clinical scenarios in terms of patient selection, procedural performance, and complication management.

Clinical Recommendation(s)

Annual reporting of the presence of a Heart Team and documented confirmation of regular meetings to review patient eligibility and treatment decisions for TAVI

Method of Reporting

The reported statistic will be a crude rate. All reporting must include a 95% confidence interval.

Reporting by region and institution with sequential trend analysis.

Challenges to Implementation/Interpretation

Need standardized documentation of the presence of a Heart Team as well as the treatment recommendation for all patients that is in an accessible format for the evaluation team.

WAIT TIME	
Description	Two components: I. Transcatheter Aortic Valve Implantation (TAVI) Evaluation time, defined as time from referral to TAVI team to Heart Team decision II. TAVI Procedural Wait time, defined as time from "Date of Heart Team decision" (i.e., consensus treatment recommendation for TAVI AND patient is ready, willing and able) to "Date of procedure".
Numerator	The number of calendar days from time of receipt of referral at the TAVI program to the date and time of procedure.
Denominator	All patients who received TAVI during the given observation period.
Method of Calculation	Wait time calculated in days as follows: I. TAVI Evaluation Time: number of calendar days from the date of initial referral to the date of heart team decision for those patients accepted for TAVI II. TAVI Procedural Wait Time: number of calendar days from date of Heart Team decision to date of TAVI procedure
Sources of Data	Clinical data available from patient charts and TAVI Heart team discussion

Rationale

Transcatheter aortic valve implantation has been demonstrated to reduce mortality compared to medical therapy in patients with severe symptomatic aortic stenosis and significant comorbidities rendering them inoperable. In addition this technology is non-inferior to surgical intervention in high-risk patients. Despite these findings the access to this technology in Canada is varied due to differences in provincial funding and the number of centers with the ability to offer this treatment. This can result in significantly long wait times for patients and in mortality for those awaiting the intervention. At present, there are no established benchmarks for wait times for TAVI and as a result it is important to gather accurate information on patients referred to for TAVI in Canada to understand the unique challenges in delivering care to this population.

Clinical Recommendation(s)

Improvement in delays associated with the evaluation process for TAVI patients to reduce wait times and improve access to care.

Method of Reporting

Reported by a median (25-75 percentile) on annual basis.

Reporting by region and institution with sequential trend analysis.

The median number of days on the TAVI wait list.

Challenges to Implementation/Interpretation

TAVI wait times will be reflective of the ability of centers to perform timely evaluations and provide access to the procedure within an appropriate time frame. One of the challenges with this indicator may be the patients themselves that request to delay the procedure for personal reasons or that require a delay for other medical reasons, including but not limited to treatment of other comorbidities, or investigations for concomitant illness. In such cases the patient is placed in "on hold" status. The time to treatment will then be calculated as the total time until procedure less the time "on hold".

Challenges to implementation of this indicator will include difficulties with documentation of date of referral and heart team decision. The committee recognizes that there will be initial challenges to collect this data however encourages the organization of TAVI programs so that such data can be collected in a more reliable fashion in the future.

PROCESS INDICATORS

EVALUATION OF PROCEDURAL RISK	
Description	In the absence of a specific risk score for Transcatheter Aortic Valve Implantation (TAVI), documentation of risk is recommended using the Society of Thoracic Surgery (STS) score in addition to documentation of a heart team discussion for those patients not deemed to be high risk by risk score calculation.
Numerator	Patients with documentation of surgical risk using the STS score.
Denominator	All patients accepted for TAVI.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	Documentation of surgical risk (STS score) in the patient assessment for TAVI from clinical charts

Rationale

Risk stratification of patients is crucial to identifying appropriate candidates for specific cardiac procedures. The EuroSCORE and Society of Thoracic Surgeons (STS) score are the most widely used risk scores to predict operative mortality in cardiac surgery. These models were developed and validated in a standard surgical risk population. The predictive power of both models is therefore suboptimal in high-risk patients with valvular disease. In the absence of a specific risk score for TAVI, some evaluation of risk must be documented for each patient and therefore in keeping with the VARC-2 recommendations, the use of the STS score is strongly recommended. This indicator will be reviewed and updated once a specific TAVI Score is available.

Clinical Recommendation(s)

All patients undergoing TAVI should have documented evaluation of procedural risk using the STS score prior to the procedure

Method of Reporting

The reported statistic will be a crude rate. All reporting must include a 95% confidence interval.

Reporting by region and institution with sequential trend analysis.

Challenges to Implementation/Interpretation

EVALUATION OF QUALITY OF LIFE	
Description	The proportion of patients with a comprehensive assessment of health related quality of life incorporating a heart failure-specific measure, Kansas City Cardiomyopathy Questionnaire, and a generic measure, EuroQoL 5D (EQ5D) to enhance compatibility and compare patients with population-level benchmarks. Quality of life should be assessed prior to the procedure (PRE) and at 12 months post-intervention (POST).
Numerator	All patients with documented evaluation of quality of life both PRE and 12 months POST Transcatheter Aortic Valve Implantation (TAVI) (within 3 months of the 12 month time frame).
Denominator	All patients who underwent TAVI procedures and survived to 12 months.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	Individual program reporting of results

Rationale

TAVI in a high risk population may be limited in its ability to prolong life due to the presence of multiple comorbidities therefore it is important to evaluate patient's quality of life after such an intervention to examine clinical benefit.

Valve Academic Research Consortium-2 recommends that a comprehensive assessment of quality of life for patients undergoing TAVI incorporate both a heart failure-specific measure (such as the KCCQ or MLHF) as well as one or more generic measures [such as the Medical Outcomes Study Short-Form 36 (SF-36), the Short-Form 12 (SF-12), or the EuroQOL (EQ-5D)] . The disease-specific measures offer improved sensitivity/responsiveness as well as clinical interpretability, whereas the inclusion of a generic health status measure is useful because it captures some additional domains. Furthermore, generic measures can enhance the comparability across different diseases and populations and can be used to compare patients with population-level benchmarks.

Clinical Recommendation(s)

Evaluation of health related quality of life using the Kansas City Cardiomyopathy questionnaire and EuroQoL 5D (EQ5D) both PRE and POST (12 months) intervention.

Method of Reporting

The reported statistic will be a crude rate on an annual basis. All reporting must include a 95% confidence interval.

Reporting by region and institution with sequential trend analysis.

Challenges to Implementation/Interpretation

Given the diversity in data collection across centers we recommend a goal of capturing KCCQ and EQ5D data in 20% of patients in the first year with a plan to reach 100% in the following four years.

LENGTH OF STAY	
Description	Number of calendar days spent in the transcatheter aortic valve implantation (TAVI) hospital following TAVI.
Numerator	The median number of TAVI hospitalization days from date of procedure to date of discharge from the procedure hospital of all patients who had TAVI and were discharged alive without a transfer to another acute care hospital.
Denominator	N/A
Method of Calculation	Length of stay = Date of discharge from TAVI centre – Date of TAVI procedure
Method of Reporting	Distribution [median (25^{th}-75^{th} percentile)] of length of stay amongst eligible patients.
Sources of Data	• Canadian Institute for Health Information (CIHI) – Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB) • Institutional clinical data • Hospital records (patient charts)

Rationale

Length of stay is associated with multifactorial patient-level, procedural and process factors.

A shorter length of stay is one of the clinical and health service benefits of TAVI compared to surgical aortic valve replacement.

Length of stay after TAVI varies across centres. This variation is due, in part, to different hospital management policies, practices and processes of care.

Longer length of stay is required to treat worse clinical outcomes after TAVI; it is associated with increased health service utilization and costs.

Clinical Recommendation(s)

Annual reporting by institution and region with sequential trend analysis by year.

Method of Reporting

- Reported by median (25^{th}-75^{th} percentile) on an annual basis.
- Method of calculation – Examples:
    - Admission from March 4-10: Length of stay = 6 days (March 10 – March 4)
    - Next-day discharge: Length of stay = 1 day

Challenges to Implementation/Interpretation

The results for this quality indicator must be interpreted with the following limitations:

- The optimal length of stay after TAVI is not known.
- Rates of inter-hospital transfer in TAVI centres vary across Canada; the true complete length of stay is not captured because the definition excludes patients who are transferred to another acute care centre after TAVI. Capturing this entire length of stay is not feasible due to the limitations of data reporting.
- Length of stay can be associated with complex determinants that may be unrelated to the quality of care:
    - Procedural approach (transfemoral, non-transfemoral).
    - Pre-procedure health status and procedural risk. Centres treating sicker/higher risk patients may report a longer median length of stay because the indicator is not risk-adjusted.
    - Delayed discharge due to social factors (e.g., social support, socio-economic resources, and travel requirements to and from TAVI centre).
    - Availability of rehabilitation placement, transferability to referring hospital for convalescence.
- Efforts to reduce length of stay could have the unintended consequence of promoting the premature discharge of patients before it is medically appropriate.
- Ideally, the reporting of length of stay should be accompanied by patient disposition at the time of discharge (e.g., return home, transfer to a rehabilitation facility) to better capture the patients' journey of care.

OUTCOME INDICATORS

30-DAY MORTALITY	
Description	Proportion of patients who died within 30 days or in-hospital from any cause after undergoing Transcatheter Aortic Valve Implantation (TAVI).
Numerator	Number of patients in the denominator and who died, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, up to and including 30 days of the procedure, and 2) those deaths occurring after discharge from the hospital, but up to and including 30 days of the procedure.
Denominator	All patients 18 years and older undergoing TAVI.
Method of Calculation	Crude mortality calculated as (numerator/denominator) x 100 (%)
Sources of Data	Canadian Institute for Health Information (CIHI) - Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB) Hospital records (patient charts) Institutional clinical data Linkage to provincial/national vital statistics.

Rationale

Mortality is regarded as an important measure of quality of care and appropriate patient selection in TAVI. Given the current limitations and variations in available data, decision has been made to use unadjusted crude mortality, which is available from administrative databases and vital statistics. This will permit institutional and regional comparisons.

Clinical Recommendation(s)

Annual reporting by institution and region with sequential trend analysis by year.

Method of Reporting

Results will be reported as crude rate (%), all reporting will include a 95% confidence interval.

Challenges to Implementation/Interpretation

Using administrative data to calculate this indicator will require linkage to provincial or national vital statistics databases.

A Canada-wide database with uniform outcome and variable definitions does not exist, however the current TVT Registry run by the NCDR in the US provides a comparator and a model to aspire to. We propose collection of such quality indicators as a first step towards the creation of a national database and a method of benchmarking individual programs.

Risk adjusted 30 day mortality might be best used as the basis for confidential continuous QI activities however at present is not a realistic goal.

When is TAVI defined, when sheath in place, when patient enters room

1-YEAR MORTALITY	
Description	Proportion of patients who died within one year from any cause after undergoing Transcatheter Aortic Valve Implantation (TAVI).
Numerator	Number of patients in the denominator and who died, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, up to and including one year of the procedure, and 2) those deaths occurring after discharge from the hospital, but up to and including one year of the procedure.
Denominator	All patients 18 years and older undergoing TAVI.
Method of Calculation	Crude mortality calculated as (numerator/denominator) x 100 (%)
Sources of Data	Canadian Institute for Health Information (CIHI) - Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB) Hospital records (patient charts) Institutional clinical data Linkage to provincial/national vital statistics.

Rationale

Mortality is regarded as an important measure of quality of care and appropriate patient selection in TAVI. Given the current limitations and variations in available data, decision has been made to use unadjusted crude mortality, which is available from administrative databases and vital statistics. This will permit institutional and regional comparisons.

Clinical Recommendation(s)

Annual reporting by institution and region with sequential trend analysis by year.

Method of Reporting

Results will be reported as crude rate (%), all reporting will include a 95% confidence interval.

Challenges to Implementation/Interpretation

Using administrative data to calculate this indicator will require linkage to provincial or national vital statistics databases.

A Canada-wide database with uniform outcome and variable definitions does not exist, however the current TVT Registry run by the NCDR in the US provides a comparator and a model to aspire to. We propose collection of such quality indicators as a first step towards the creation of a national database and a method of benchmarking individual programs.

Risk adjusted one year mortality might be best used as the basis for confidential continuous QI activities however at present is not a realistic goal.

IN-HOSPITAL STROKE	
Description	Stroke, defined as an acute episode of focal or global neurological dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction, occurring after Transcatheter Aortic Valve Implantation (TAVI) and during the index admission for TAVI procedure as confirmed by either brain imaging or documentation of a neurologist.
Numerator	Patients who underwent TAVI procedures and suffered stroke during the same hospitalization.
Denominator	All patients who underwent TAVI procedures.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	Canadian Institute for Health Information (CIHI) - Discharge Abstract Database (DAD)/Hospital Morbidity Database (HMDB) Institutional clinical data Hospital records (patient charts)

Rationale

Stroke is an important peri-procedural complication of TAVI and can have significant consequences for the patient, their quality of life and their ability to rerun to independent living.

Clinical Recommendation(s)

Method of Reporting

Results reported as a crude rate (%) on an annual basis. All reporting must include a 95% confidence interval.

Reporting by region and institution with sequential trend analysis

Challenges to Implementation/Interpretation

Although the occurrence of stroke at 30 days is the ideal measure, the working group recognizes the challenges in obtaining such data in particular given that many patients may be treated far from their local hospital. As a result, in order to capture the rates of stroke related to the TAVI procedure there was a consensus to obtain rates from the TAVI hospitalization. Ideally we would like to obtain data on disabling vs. non-disabling stroke but it may be difficult to obtain initially.

There will be a difficulty to capture all in-hospital stroke for patients transferred to other health care facilities.

30-DAY ALL CAUSE HOSPITAL READMISSION	
Description	The proportion of patients with a readmission to an acute care facility for any cause within the 30 days of discharge for the index admission for the Transcatheter Aortic Valve Implantation (TAVI) procedure.
Numerator	Number of patients in the denominator who experience a readmission to any hospital for any cause within the 30 days following TAVI.
Denominator	All patients undergoing TAVI and who were discharged alive from an acute care hospital from index hospital stay.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	Discharge Abstract Database (DAD), Hospital Morbidity Database (HMDB), Canadian Institute for Health Information, and institutional clinical databases.

Rationale

Increased emphasis is being placed on 30-day rates of readmission as a metric by which quality of acute care may be gauged. While the reasons underlying readmissions to hospital may vary from patient to patient, common mechanisms may exist by which to reduce these encounters across all cardiac surgical centers. This metric is not commonly reported or available.

Clinical Recommendation(s)

Improvement in the rate of 30-day all-cause readmission to hospital following TAVI.

Method of Reporting

Results will be reported as crude rate (%)

Challenges to Implementation/Interpretation

Rates of 30-day all-cause readmission is a broad variable that neither indicates when the patient is typically being readmitted, to which hospital they are being readmitted, and for what reason they are being readmitted. While rates of 30-day all-cause readmission will undoubtedly serve as a valuable quality metric, further study will be needed to better understand the mechanisms underlying these rates so that interventions may be established to reduce rates of readmission as needed.

Need clarification on in-hospital transfers

Kaplan-Meier method for re-hospitalization

1-YEAR ALL CAUSE HOSPITAL READMISSION	
Description	The rate of readmission to an acute care facility for any cardiac cause on or before one year (365 days) following discharge for the Transcatheter Aortic Valve Implantation (TAVI) procedure.
Numerator	Number of patients in the denominator who experience a readmission to any hospital for any cause on or before one year following discharge for TAVI.
Denominator	All patients undergoing TAVI and who were discharged alive from hospital within one year.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	Discharge Abstract Database (DAD), Hospital Morbidity Database (HMDB), Canadian Institute for Health Information, and institutional clinical databases.

Rationale

Rate of readmission is regarded as an important measure of quality of care and appropriate patient selection in TAVI. High rates of hospital readmissions may indicate inappropriate care or selection of TAVI patients.

Clinical Recommendation(s)

Method of Reporting

Results will be reported as crude rate (%) on annual basis. All reporting must include a 95% confidence interval.

Reporting by region and institution with sequential trend analysis

Challenges to Implementation/Interpretation

NEW PERMANENT PACEMAKER RATE	
Description	Proportion of patients who received a new permanent pacemaker after undergoing transcatheter aortic valve implantation (TAVI).
Numerator	Patients who had TAVI and had a new permanent pacemaker implantation during the index hospital stay at the TAVI hospital.
Denominator	All patients who underwent TAVI and had no prior permanent pacemaker.
Method of Calculation	Crude rate calculated as numerator/denominator x 100 (%)
Sources of Data	• Canadian Institute for Health Information (CIHI) – Discharge Abstract Database (DAD) • Institutional clinical data • Hospital records (patient charts)

Rationale

TAVI can result in impaired atrio-ventricular conduction; this may increase the need for electrocardiographic monitoring, temporary pacemaker, or permanent pacemaker implantation.

The need for a new permanent pacemaker has implications for increased use of health care resources related to in-hospital monitoring, longer length of stay, and long term management; it is associated with worsening left ventricular function and morbidity; it may impact life expectancy and quality of life.

Clinical Recommendation(s)

Annual reporting by institution and region with sequential trend analysis by year.

Method of Reporting

Results reported as a crude rate (%) on an annual basis. All reporting must include a 95% confidence interval.

Challenges to Implementation/Interpretation

The accurate documentation of existing pacemaker is required to assess the new pacemaker rate.

ACKNOWLEDGEMENTS

The Canadian Cardiovascular Society acknowledges and sincerely thanks the following individuals in the development of this Quality Indicators Cardiac Surgery Chapter:

Quality Indicators Transcatheter Aortic Valve Implantation Working Group (QI-TAVI-CWG)
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Eric Cohen, Sunnybrook Health Sciences
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Neville Suskin, London Health Sciences Centre
Robert Welsh, University of Alberta

Project Support
Kendra MacFarlane, Coordinator, Health Policy and Advocacy, Canadian Cardiovascular Society

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