CANADIAN CARDIOVASCULAR SOCIETY

TOOLKIT: TRANSCATHETER AORTIC VALVE IMPLANTATION

2019
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TAVI TOOLKIT OVERVIEW

The TAVI toolkit has been developed in an effort to:

• Complement the CCS TAVI Quality Indicators (QIs);
• Improve the data quality of the CCS TAVI Quality Report by providing guidance, resources, and practice-ready strategies;
• Strengthen collaboration and on-going commitment to the CCS TAVI Quality Report initiative;
• Share resources and capitalize on local initiatives to accelerate national quality improvement; and
• Support clinicians and programs to optimize care.

This module introduces the framework used to develop a suite of individual modules built to augment the CCS TAVI Quality Indicators.
INTRODUCTION
THE CCS TAVI QUALITY PROJECT

The CCS TAVI Working Group was established in 2014 to build a strategy for reporting and supporting quality of care in Canada. The group has multidisciplinary and pan-Canadian representation. It is guided by a vision to use evidence and clinical expertise to promote continuous quality improvement through a series of cycles involving analysis, strategy and implementation.

Figure 1. Quality Indicators Improvement Cycle
THE CCS TAVI QUALITY INDICATORS AND REPORT

The CCS TAVI Working Group established the first iteration of quality indicators in 2016 using the Donabedian framework of quality improvement. As of 2019, the Working Group has established the following set of quality indicators:

**Structural**
- Heart Team treatment recommendation
- TAVI wait time

**Process**
- Evaluation of procedural risk
- Evaluation of quality of life
- Length of stay

**Outcomes**
- Mortality for TAVI
- In-hospital stroke post-TAVI
- All cause hospital readmission
- New permanent pacemaker rate

Figure 2. Structural, process, and outcome quality indicators for TAVI in Canada

The indicators match key components of TAVI patients’ journey of care:

**TAVI Patient’s Journey**

- Pre-Procedure
  - Evaluation of Procedural Risk
  - Evaluation of Baseline Quality of Life
  - Heart Team Approach to Treatment Recommendation

- Peri-Procedure
  - In-Hospital Stroke
  - Length of Stay
  - New Permanent Pacemaker Rate

- Follow-Up
  - 30-Day Mortality
  - 30-Day All Cause Readmission
  - 1 Year Mortality / Year All Cause Readmission
  - 1 Year Quality of Life

Figure 3. Quality Indicators for TAVI in Canada

Following the development of the QIs, the CCS initiated a pilot project to pool and report on patient-level data across Canadian jurisdictions. The pilot project resulted in the 2016 CCS National Quality Report: TAVI whose objectives are to:

- Strengthen national collaboration to promote quality of care;
- Provide evidence-based findings to catalyze local, regional and national quality improvement;
- Support patients’ access to appropriate, high quality care;
- Foster a national strategy to optimize patient outcomes, health service utilization, and access to treatment.
THE CCS TAVI TOOLKIT

Following the first TAVI Report, there was strong national interest in strengthening the bridge between data reporting, clinical practice, and quality improvement. This led to the development of the CCS TAVI Quality Toolkit.

The intent of the Toolkit is to contribute to improvements in the quality of care across Canada. The project will keep pace with the addition of new quality indicators, and provide a central repository for sharing resources and best practices to contribute to the improved outcomes of Canadian TAVI patients.

Figure 4. Geographical locations of TAVI centres in Canada

Each TAVI Toolkit module includes the following sections:

1. Definition of the indicator
2. Opportunities and challenges of measurement
3. Practical tips and best practices
4. Questions and answers
5. Resources

Technical terminology used throughout each module is listed in our Common Abbreviations document.

THE CCS TAVI TOOLKIT: STRENGTHS AND LIMITATIONS

The intent of the Toolkit is to provide guidance and resources; it was developed by national stakeholders who collaborated to share their expertise and build consensus. The Toolkit is strengthened by the extensive input from multiple national leaders with varying perspectives. It provides a practice-ready set of resources for program leaders, including TAVI coordinators, administrators and policy-makers in addition to physician leaders.

The goal of providing pragmatic resources that reflect contemporary practice, coupled with a rapidly evolving context of care limit the inclusion of extensive evidence. Extensive references are not provided as most of the information reflects expert opinion. Therefore, readers should use caution when considering the information provided; emerging evidence and local contexts of care should be considered.
## TAVI – USEFUL LINKS

### GUIDELINES
- **CCS TAVI Position Statement**
- Updated position statement in development
- **American College of Cardiology (ACC) Clinical Expert Consensus**
- **Clinical Practice Guideline, British Medical Journal (BMJ)**
- 2014 ACC/American Heart Association (AHA) Practice Guidelines
- 2017 ACC/AHA Practice Guidelines update

### QUALITY STANDARDS
- 2016 Canadian Cardiovascular Society National Quality Report: TAVI
- Quality Standards for Québec
- **AHA Appropriateness Criteria**

### PERTINENT SCIENTIFIC ARTICLES
- Systematic review of the literature (French)

### TAVI REGISTRIES
- Society for Thoracic Surgeons (STS)/ACC TVT Registry

### PATIENT EVALUATION TOOLS
- Frailty AVR study (2016)
- **Kansas City Cardiomyopathy Questionnaire (KCCQ)**
- EQ-5D
- Mini-Cog
- Activities of daily living (FIM)

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WAIT TIME QUALITY INDICATOR MODULE

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MODULE OVERVIEW
In this module, users are provided with:
• Key TAVI wait time definitions;
• Reasons for documentation;
• Key recommendations;
• Common questions and answers; and
• Examples of reporting of TAVI wait list activities.

Following review of this module, users will have a more thorough understanding of this structural indicator and be better equipped to document and interpret TAVI wait time information.
1. CCS QUALITY INDICATOR DEFINITION

The measurement of the wait time quality indicator aims to capture the trajectory from the day of referral to the completion of the procedure to reflect patients’ experience of waiting.

Table 1. TAVI Wait Time (CCS Quality Indicator)

| Description | Two components:  
| | I. 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  

To this end, three different time periods were selected:

Time 1: From referral to a heart team treatment decision [TAVI Evaluation Wait Time];
Time 2: From a heart team treatment decision to the procedure [TAVI Procedural Wait Time];
Total TAVI Wait Time: From referral to procedure (Time 1 + Time 2)
2. OPPORTUNITIES AND CHALLENGES

Opportunities: The accurate and timely capture and reporting of wait times is essential to improve clinical wait list management, programmatic planning, and funding allocation. The availability of accurate and standardized measurement of wait times enables cross-regional comparisons and promotes equity of access to care across Canada.

Challenges: Canadian centres have reported the following challenges in monitoring and reporting of wait time:

- Lack of standardized definitions of wait time points
  - When is the patient “point of entry” into the TAVI program? When is a patient considered “referred for TAVI” along the continuum of chronic disease management and who is (are) the health care provider(s) involved?
  - What clinical activity captures the heart team’s treatment decision?
- Inconsistent capture of clinical delays or patient choice
  - How do we measure delays associated with a patient being placed “on hold” due to personal needs or clinical status while under assessment or on the wait list?
- Coordination and delegation of responsibility for data capture
  - Whose job is it to document the time points, manage the wait list, and measure delays?
  - How can we report and examine deaths of patients who were undergoing assessment or waiting for the procedure?
  - How can we communicate wait time measures and outcomes to administration, funders, and policy-makers?
3. PRACTICAL TIPS AND BEST PRACTICES

Definitions

Date of Referral: The intent is to capture the date when a referral is made from a physician who knows the patient’s clinical status (e.g., cardiologist, internist) and believes the patient may benefit from TAVI (i.e., referral is accepted). TAVI programs have different practices related to acceptance of a referral. For the purposes of wait time reporting, a referral can be provided in writing or verbally.

The definition can be adapted to two models of care:

1. If the TAVI program is centrally coordinated: Date on which the referral is received by the TAVI program (e.g., by the TAVI Coordinator);
2. If a TAVI physician manages referrals independently: Date when the TAVI physician receives the referral. If the program includes more than one physician, a single member of the team should be tasked with responsibilities for wait list activities and reporting. This physician is responsible for communicating the date of referral to the TAVI program in a timely manner. The TAVI program records the date of referral provided by the TAVI physician.

Date of Acceptance: The intent is to capture the date when the Heart Team has the necessary information required to recommend TAVI. It is assumed that the patient confirms shortly after that he or she is ready, willing, and able to undergo the procedure.

• Date on which the Heart Team makes a treatment recommendation for TAVI.
• Best practice: The TAVI Coordinator or other delegated team member contacts the patient to confirm that he/she wishes to be placed on the wait list, and is ready, willing, and able to have the procedure when scheduled.

Placed on Hold: The intent is to subtract the time when a patient’s clinical status (e.g., hospitalization, clinical deterioration related to a health problem that delays TAVI) or personal needs (e.g., travel, family events) prevents the completion of the assessment or procedure. Time spent on hold (e.g., unavailable for care) can jeopardize accurate wait time reporting.

• Best practice: The time when placed “on hold” is subtracted from the time under assessment (between date of referral and date of acceptance), or from the time on the wait list (between the date of acceptance and date of procedure). A patient ought to be on the waitlist only when ready, willing, and able.

Date of Procedure: The intent is to capture the date when TAVI was performed. The date of admission can be different from the day of procedure.
The time points of TAVI patients’ journey from referral to procedure are illustrated as follows:

Figure 2. Standardized time points of TAVI patients’ journey from referral to procedure (Adapted from CorHealth Ontario)

Treatment Decision
Canadian TAVI centres are encouraged to monitor the treatment decision for all patients referred for TAVI. If ineligible for TAVI, other options include a new or repeat referral for surgical aortic valve replacement, on-going medical surveillance (e.g., for asymptomatic patients), and referral for palliative approach to improve symptom management in cases where treatment is deemed futile.

Recommendations
- Consider central referral to TAVI program with engagement of a medical director [program cardiologist(s) and/or cardiac surgeon(s)] to optimize coordination of care;
- Adopt standardized definitions of time points;
- Consider a wait list management tool;
- Develop a regular wait list activity report shared routinely with clinicians, administrators and policy-makers;
- Monitor and report deaths under assessment and on wait list; and
- Consider monitoring treatment decision of all patients referred for TAVI to track case selection.

Wait Time Benchmarks
Wait times have consequences such as patient mortality, morbidity in the form of repeated hospitalizations, and functional deterioration. There is limited evidence to determine appropriate wait times based on clinical status and urgency. The updated CCS TAVI Position Statement (expected for release in 2019) will include recommended benchmarks from decision to procedure for in-patients and out-patients.
4. QUESTIONS AND ANSWERS

In our centre, patients are referred verbally from physician to physician, in person or by telephone. What is the date of referral?

In this case, the referral is made to the TAVI program through the TAVI physician. It is the TAVI physician’s responsibility to document and communicate the date of referral (i.e., date of physician to physician conversation, and acknowledgement that the TAVI physician accepts the referral) to the TAVI program. The intent is to capture the date the TAVI physician accepts the referral and begins the eligibility assessment.

How should the time points be documented for in-patients?

Similar to elective out-patients, the date of referral is the date a referring physician contacts a TAVI physician to request assessment for eligibility for TAVI. The date of acceptance is the date the TAVI physician or delegate documents that the Heart Team has made a treatment recommendation. It is assumed that the patient is ready, willing, and able to have the procedure at any point (i.e., all diagnostic tests are completed, and the patient has agreed to undergo the procedure).

How should the time points be documented if the patient is discussed repeatedly by the TAVI Heart Team?

The date of referral is the first date the referral is accepted by the program unless significant time has lapsed and the referral is considered a new repeat referral. The time points for a repeat referral are measured from the time the new referral is made (i.e., counts as a new patient encounter). The careful documentation of time “placed on hold” is particularly important for this group of patients.

Some of our referrals are inappropriate. For example, we might be asked to assess a patient who is asymptomatic or a low surgical risk patient, or is excessively frail and at end of life. These patients are not usually discussed by the Heart Team, based on the input of TAVI physicians. Should we capture Time 1 for this category of patient?

No. The intent is to capture the wait list activities of patients who will be discussed by the Heart Team. Some centres have managed this issue by formalizing physicians’ acceptance of the referral (i.e., accepting the patient for assessment and treatment decision).
5. RESOURCES

The following resources are provided for reference only.

CorHealth Ontario uses the Wait Time Information System (WTIS) to track, monitor, and collect data on patients waiting for select cardiac procedures, including TAVI. The ‘My Encounters’ table within the WTIS (Figure 4) is a tool that hospitals can use to identify which patients are currently waiting for a procedure, what procedure they are waiting for, how long they have been waiting, and how that time compares to their Recommended Maximum Wait Time (RMWT). Each hospital has access to patients waiting for select cardiac procedures at their respective facility. With respect to TAVI, there is no accepted RMWT in Ontario and these fields are typically left blank.

![Figure 3. Example of reporting of wait list activities (CorHealth Ontario)](image)

Please Note: The data is fictional and is presented for illustration purposes only.
Cardiac Services BC (CSBC) reports wait list activities for transfemoral and non-transfemoral TAVI every fiscal period for each provincial site and the province as a whole. Although there is no established recommended maximum wait time for TAVI, CSBC has adopted reporting standards applied to surgical valve replacement to support planning and coordination. The reporting is routinely accompanied by a description of context and an expectation that each site is monitoring and managing each patient’s wait time in light of his or her clinical status with appropriate queuing.

Figure 4. Example of reporting of wait list activities (Cardiac Services BC)\textsuperscript{4}

Please Note: The data is fictional and is presented for illustration purposes only.

The CSBC Wait List Activity Report contains multiple variables that enable the monitoring of “real time” data in addition to temporal trends.

- Data is presented by fiscal period;
- The Blue Bars represent the count of patients who were added to the wait list (accepted for TAVI and ready, willing, and able);
- The Black Line represents the count of patients who were on the wait list on the last day of the fiscal period;
- The Pink Dotted Line represents the number of patients who were on the wait list and were exceeding a target wait time (<42 days) on the last day of the fiscal period;
- The Lilac Bars represent the count of elective out-patients who were removed from the wait list (procedures completed or removed from wait list for clinical or personal reasons);
- The Peach Bars (below the Lilac Bars) represent the count of urgent in-patients who were removed from the wait list;
- The Orange Line represents the count of procedures completed on patients who were exceeding the target wait time (<42 days) on the day of their procedure (indicator of appropriate queueing);
- The Red Bars represent the count of patients who died on the wait list.
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SOURCES

MODULE OVERVIEW

The TAVI Toolkit evaluation of procedural risk module provides resources to improve the quality of data collection by discussing:

• Key TAVI procedural risk definitions;
• Practical tools for calculating procedural risk;
• Case studies for practice; and
• Helpful resources.

Users will also find an extensive list of STS variable definitions in Appendix I. Following review of this module, users will be aware of a variety of resources to support them in measuring this process indicator.
1. CCS QUALITY INDICATOR DEFINITION

The measurement of procedural risk quality indicator aims to capture predicted risk of operative mortality for surgical aortic valve replacement that can inform TAVI case selection and adherence to current indications. The CCS TAVI Working Group selected the Society of Thoracic Surgeons’ (STS) Risk Score as the recommended measurement tool.

The CCS TAVI Quality Report documents the proportion of patients with STS measurement at baseline (i.e., time of eligibility assessment).

Table 1. Evaluation of procedural risk (CCS Quality Indicator)

<table>
<thead>
<tr>
<th>Description</th>
<th>In the absence of a specific risk score for TAVI, documentation of risk is recommended using the STS score in addition to documentation of a heart team discussion for those patients not deemed to be high risk by risk score calculation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Numerator</td>
<td>Patients with documentation of surgical risk using the STS score.</td>
</tr>
<tr>
<td>Denominator</td>
<td>All patients accepted for TAVI.</td>
</tr>
<tr>
<td>Method of Calculation</td>
<td>Crude rate calculated as numerator/denominator x 100 (%)</td>
</tr>
<tr>
<td>Sources of Data</td>
<td>Documentation of surgical risk (STS score) in the patient assessment for TAVI from clinical charts</td>
</tr>
</tbody>
</table>

2. OPPORTUNITIES AND CHALLENGES

Opportunities

- STS is routinely used in international registries and clinical trials to describe patient cohorts and report on case selection. There is utility in comparing Canadian data to other regions and benchmarking clinical trials.
- The STS Online Risk Calculator can be freely accessed online.
- The STS Training Manual contains the complete variable definitions and can be freely accessed online.

Challenges

- The STS score model was developed and validated in the US cardiac surgery population. The purpose of the score is to capture surgical risk. It does not fully account for co-morbidities pertinent to the TAVI population, such as severe respiratory disease, porcelain aorta and frailty. Thus, the STS score may underestimate the true surgical risk of patients considered for TAVI. The CCS TAVI Working Group recognizes that STS is only a surrogate measure of the “true” risk of TAVI.
- The American College of Cardiology (ACC)/STS TAVR In-Hospital Mortality Risk Calculator is a novel risk estimate. It was developed from the data of nearly 14,000 consecutive patients treated in US sites between 2011 and 2014, and further validated in a subsequent cohort over nearly 7,000 patients treated in 2014. The ACC/STS recommends that the score be used for local quality improvement, monitoring for appropriateness of case selection, and guidance in the overall conversation about the TAVR procedure. It should not be used as a recommendation for or against any medical procedure. The model includes the highest risk indicators (i.e., renal function/dialysis, procedure access site, New York Heart Association (NYHA) Class IV, severe chronic lung disease, acuity status, prior cardiac arrest, prior cardiogenic shock, pre-procedure inotropes and mechanical device). In the future, the TAVR Risk Calculator will be strengthened with on-going prospective data collection, inclusion of new variables, and modelling of 30-day mortality. Currently, the score has limited utility in the evaluation of risk in contemporary TAVI in Canada but may be considered in the future.
3. PRACTICAL TIPS AND BEST PRACTICES

Data Collection

The calculation of the STS score is a specialized skill requiring clinical interpretation and should be done by a clinician who understands the variable definitions. This is not a clerical task. The inter-rater reliability can be jeopardized if the score is performed by individuals without training and in the absence of quality assurance measures. Responsibility can be delegated to a healthcare professional (e.g., TAVI Coordinator) who receives appropriate training by physicians and is supported with on-going training and quality assurance (e.g., regular checks with feedback).

Variable Definitions

- The STS Online Calculator includes variable definitions that are available by toggling above the field.
- The risk score calculation is performed for “AV Replacement” or “AV Replacement + CAB” if the patient needs coronary revascularization (regardless of whether percutaneous coronary intervention is planned/perform)ed):

Figure 1. Opening View of the STS Online Calculator²
STS Calculation and Interpretation

The indicator that is used to document procedural risk in the CCS TAVI Quality Report is the STS predicted risk of 30-day mortality:

Figure 2. Online view of an example of STS AV Replacement procedural risk calculation

The STS Online Calculator generates other predicted surgical risks: Morbidity or mortality, long (>14 days) or short (<6 days) length of stay, permanent stroke, prolonged ventilation, deep sternal wound infection, renal failure, and rehospitalisation.

The STS surgical risk scores for 30-day mortality are stratified as low (<4%), intermediate (4-8%), and high (> 8%).
## STS Calculation Case Studies

The following are case studies that can be used for training team members to calculate the STS score accurately. The exact score may change over time because the modelling is updated regularly.

### Case Study #1: AV Replacement

- **Demographics:** 84-year-old woman, 165 cm, 92 kg.
- **Cardiac Presentation:** Severe AS (no concomitant valve disease); LVEF 50%; no angina; no prior MI/PCI/CABG; permanent AF; hypertensive (144/80); peripheral artery disease; no previous cardiac interventions or surgery.
- **Co-morbidities:** Creatinine 115umol/L; documented moderate lung disease; no previous CVA or peripheral arterial disease; DM on oral hypoglycemic; no history of immunosuppression or active infection.
- **Status:** Elective out-patient with stable clinical status.

Case 1 – STS Predicted Risk of Mortality: 4.9%

### Case Study #2: AV Replacement

- **Demographics:** 78-year-old man, 177 cm, 78 kg.
- **Cardiac Presentation:** Regular sinus rhythm (HR 70); BP 92/50 (no antihypertensive) on low dose milrinone; severe AS and moderate mitral insufficiency; LVEF 40%; currently admitted with new onset of heart failure and NYHA III; stable angina with remote history of MI and PCI to LAD and Circumflex (> 60% in both vessels but no LM disease); hypertensive (144/80); no previous cardiac interventions or surgery.
- **Co-morbidities:** Creatinine 115umol/L; history of emphysema with FEV1 48; prior CVA and history of claudication; no DM, immunosuppression, or active infection.
- **Status:** Urgent in-patient; no previous resuscitation.

Case 2 – STS Predicted Risk of Mortality: 8.5%

### Case Study #3: AV Replacement

- **Demographics:** 89-year-old woman, 150 cm, 52 kg.
- **Cardiac Presentation:** New onset of paroxysmal AF HR 88; BP 150/90; severe AS and moderate mitral insufficiency; LVEF 40%; currently admitted with new onset of heart failure and NYHA III; stable angina with remote history of MI and PCI to LAD and Circumflex (> 60% in both vessels but no LM disease); hypertensive (144/80); previous surgical AVR (referred for valve-in-valve TAVI); RSR.
- **Co-morbidities:** On dialysis: Creatinine 620 umol/L (7mg/dL); no history of lung disease, CVA, peripheral arterial disease, diabetes, immunocompromise, or active infection.
- **Status:** Elective out-patient; no previous resuscitation; stable clinical status.

Case 3 – STS Predicted Risk of Mortality: 19.0%
4. QUESTIONS AND ANSWERS

The patient requires coronary revascularization in addition to AVR. Do I select “AVR” or “AVR + CAB” to calculate the STS for TAVI?

Select AVR + CAB.

The patient has a history of PVCs. Does this qualify as a Cardiac Arrhythmia in the score calculation?

Select “Yes” for “Cardiac Arrhythmia” and “None” for “AF”.

The patient has a history of hypertension but is normotensive on medications. Should “RF-Hypertension” be labelled “Yes” or “No”?

Select “Yes” because treated hypertension remains a risk factor.

5. RESOURCES

- STS Online Risk Calculator
- STS Training Manual
- ACC/STS TAVR In-Hospital Mortality Risk Calculator

Variables Definitions

Variable definitions, which should be highlighted in the training program and can be used as an on-going resource to maintain data quality, can be found in Appendix I.

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### APPENDIX I. STS VARIABLE DEFINITIONS

STS variable definitions have been adapted from the STS manual available online.3

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>DEFINITION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemo Data-EF Done</td>
<td>Measured prior to the induction of anesthesia</td>
<td>EF can be obtained by echo or cardiac catheterization.</td>
</tr>
<tr>
<td>HF within two weeks</td>
<td>Physician documentation or report of clinical symptoms of heart failure</td>
<td>A low EF alone, without clinical evidence of heart failure, or an elevated BNP without other supporting documentation do not qualify as heart failure.</td>
</tr>
<tr>
<td>Race Documented</td>
<td></td>
<td>Race is not routinely collected in Canadian health records used for risk scoring. Not required.</td>
</tr>
<tr>
<td>RF – Renal Fail-Dialysis</td>
<td>Hemodialysis or peritoneal dialysis</td>
<td></td>
</tr>
<tr>
<td>RF – Last Creat Level</td>
<td>Most recent blood creatinine</td>
<td>Convert SI Units (umol/L) to C Units (g/dL) [Normal: 50-110 umol/L or 0.6-1.2 mg/dL].</td>
</tr>
<tr>
<td>Cardiac Presentation/ Symptoms (At Time of This Admission)</td>
<td>Angina/ACS at the time of assessment</td>
<td>• Stable: No change in frequency or pattern for six weeks prior to TAVI; • Unstable: Includes one angina at rest, two new onset &lt; 2 months, three increasing angina (intensity, duration, frequency); • Equivalent: Symptom such as dyspnea, diaphoresis, extreme fatigue, or pain at a site other than the chest, occurring in a patient at high cardiac risk.</td>
</tr>
<tr>
<td>Prior MI</td>
<td>Documented previous MI at any time prior to this surgery/TAVI</td>
<td>See training manual for definition of MI Capture time frames: • ≤ 6 hours • &gt; 6 to &lt; 24 hours • 1 to 7 days • 8 to 21 days • &gt; 21 days</td>
</tr>
<tr>
<td>Cardiac Arrhythmia</td>
<td>History of a cardiac rhythm disturbance</td>
<td>Includes any documented cardiac arrhythmia.</td>
</tr>
<tr>
<td>AF</td>
<td>History of AF</td>
<td>• Paroxysmal: Spontaneous termination within seven days and most often &lt;48 hours; • Continuous/Persistent: Not self-terminating; lasts longer than 7 days; or prior cardioversion; • None: Currently in normal sinus rhythm.</td>
</tr>
<tr>
<td>RF – Chronic Lung Disease</td>
<td>Presence and severity of chronic lung disease</td>
<td>• No: No lung disease; • Mild: FEVI 60-75% of predicted, and/or chronic inhaled or oral bronchodilator therapy; • Moderate: FEVI 50-59% of predicted, and/or chronic steroid therapy aimed at lung disease; • Severe: FEVI &lt; 50% predicted, and/or Room Air pCO2 &gt; 50; • Lung disease documented, severity unknown: e.g., history of chronic inhalation reactive disease, COPD, chronic bronchitis, emphysema (patients with asthma or seasonal allergies are not considered to have chronic lung disease); • Unknown: Not known and not documented.</td>
</tr>
<tr>
<td>VARIABLE</td>
<td>DEFINITION</td>
<td>COMMENTS</td>
</tr>
<tr>
<td>--------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| RF – Cerebrovascular Disease | Includes history of:  
(1) Stroke;  
(2) Transient ischemic attack;  
(3) Non-invasive or invasive arterial imaging test demonstrating ≥ 50% stenosis of major cranial vessels; or  
(4) Previous cervical or cerebral artery revascularization surgery or percutaneous intervention | Cerebrovascular disease does not include chronic (nonvascular) neurological diseases or other acute neurological insults such as metabolic and anoxic ischemic encephalopathy. |
| RF – Prior CVA       | An acute episode of focal or global neurological dysfunction caused by brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction, where the neurological dysfunction lasts for longer than 24 hours.                               |                                                                                                                                             |
| RF – Peripheral Arterial Disease | History of upper and/or lower extremity, renal, mesenteric, and abdominal aortic systems arterial disease |
|                      | • Claudication: With exertion or rest;  
• Amputation: For arterial vascular insufficiency; vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (does not include vein stripping);  
• Documented abdominal aortic aneurysm with or without repair;  
• ABI ≤ 0.9; MRI or CT evidence of > 50% diameter stenosis in any peripheral artery, or angiographic evidence of peripheral arterial evidence. |                                                                                                                                             |
| RF – Diabetes        | History of diabetes diagnosed and/or treated by a healthcare provider                                                                                                                                      | Select most aggressive therapy:  
• Diet only;  
• Oral agent (with or without diet);  
• Insulin (any combination with insulin);  
• Other adjunctive treatment;  
• None;  
• Unknown.                                                                                                                                   |
| RF – Hypertension    | Document if:  
• Diagnosed and treated with medication, diet, and/or exercise; SBP>140 and/or DBP>90 (if no diabetes or chronic kidney disease), or  
• SBP>130 and/or DBP>80 (if diabetes or chronic kidney disease).                                                                                     | |
| RF – Immunocompromise | Immunosuppressive therapy within 30 days                                                                                                                                                                     | Includes systemic steroid therapy, anti-rejection medications and chemotherapy; Does not include topical steroid applications, one time systemic therapy, inhaled steroid therapy or pre-procedure protocol. |
| RF – Endocarditis    | History of endocarditis that meets at least one criteria:  
1. Organisms cultured from valve or vegetation; or  
2. (2) Two or more symptoms (see list)                                                                                                            | Choose “Yes” for patients with pre-operative endocarditis who begin antibiotics post-operatively.  
• Treated: No antibiotic medication (other than prophylactic medication) is being given at the time of surgery;  
• Active: The patient is currently being treated for endocarditis.                                                               |
<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>DEFINITION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Anatomy/ Disease known</td>
<td>Document if coronary artery anatomy and/or disease is/are documented and available prior to surgery/TAVI. If CAD is known, indicate number of diseased major native vessel systems: 1. One of LAD system, or Circumflex system, or RCA system with ≥ 50% stenosis; 2. Two of LAD system, or Circumflex system, or RCA system with ≥ 50% stenosis; or Left Main disease with ≥ 50% stenosis; 3. LAD system and Circumflex system and RCA system with ≥ 50%; or One of LAD system, or Circumflex system, or RCA system with ≥ 50% stenosis AND Left Main disease with ≥ 50% stenosis. A vessel that has ever been considered diseased should always be considered diseased. If a coronary artery has a stent in place, determine the stenosis of the native artery prior to the stent.</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td>Clinical status prior to surgery/TAVI</td>
<td>Most TAVI patients fall under these categories:  • Elective: Out-patient;  • Urgent: In-patient.</td>
</tr>
<tr>
<td>Resuscitation</td>
<td>Cardiopulmonary resuscitation before the start of TAVI (includes CPR at the institution of anesthetic management)</td>
<td>Capture resuscitation timeframe within 1 hour <em>or</em> between 1 and 24 hours pre-op.</td>
</tr>
<tr>
<td>Cardiogenic Shock</td>
<td>Development of cardiogenic shock before undergoing TAVI: &gt; 30 min episode of hypoperfusion (SBP&lt;90 mmHg, CI &lt;2.2 L/min/m2, and/or IV inotropic or vasopressor or mechanical support)</td>
<td>Capture cardiogenic shock timeframe within 1 hour <em>or</em> between 1 and 24 hours pre-op. Transient episodes of hypotension reversed with IV fluid or atropine do not constitute cardiogenic shock.</td>
</tr>
<tr>
<td>Classification – NYHA</td>
<td>Worst dyspnea or functional class, coded as the NYHA classification within the past two weeks</td>
<td>• Class I: No limitations of ADL's. Limiting symptoms may occur with marked exertion;  • Class II: Slight limitation of ADL's. Patient is comfortable at rest. Ordinary physical activity results in fatigue, dyspnea and anginal pain;  • Class III: Marked limitation of physical activity. Patient comfortable at rest. Less than ordinary physical activity causes fatigue, dyspnea and angina;  • Class IV: Subjects with cardiac disease resulting in inability to participate in any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.</td>
</tr>
<tr>
<td>IABP</td>
<td>Placed on an IABP</td>
<td>Capture time frame:  • Pre-operatively;  • Intra- operatively;  • Post- operatively.</td>
</tr>
<tr>
<td>Meds – Inotropes</td>
<td>Administration of IV inotropic agents within 48 hours preceding surgery/TAVI.</td>
<td></td>
</tr>
<tr>
<td>VARIABLE</td>
<td>DEFINITION</td>
<td>COMMENTS</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Prev Cardiac Intervent | Any previous cardiovascular intervention, either surgical or non-surgical, which may include those done during the current admission | Document any previous PCI any time prior to this surgery/TAVI. Capture time frame:  
• ≤ 6 hours;  
• > 6 hours. |
| VD – Mitral, Aortic, Tricuspid | Presence of valve disease  
• Mitral: Stenosis and/or Insufficiency  
• Aortic: Stenosis and/or Insufficiency  
• Tricuspid: Insufficiency | Capture severity of insufficiency:  
• Enter level of valve function associated with highest risk (i.e., worst performance);  
• Enter the highest level recorded in the chart;  
• ‘Moderately severe’ should be coded as ‘Severe’. |
| Incidence | Previous surgery: Defined as cardiothoracic operations (heart or great vessels) performed with or without CPB, and lung or tracheal procedures utilizing CPB | Document first or repeat CV surgery. |
| Prev CAB | Previous CABG prior to the current admission. |                                                                                                       |
| Prev Valve | May include percutaneous valve procedures (i.e., repeat TAVI). |                                                                                                       |
MODULE OVERVIEW

The TAVI Toolkit QOL module provides users with:

• Definition of health-related QOL and associated domains;
• Opportunities and challenges of measuring QOL;
• Common questions and answers;
• Helpful resources.

Following review of this module, users will have an appreciation for the importance of measuring this process indicator.
I. CCS QUALITY INDICATOR DEFINITION

The measurement of QOL quality indicator aims to improve patient selection and augment outcome evaluation by reporting on reliable measurements of patients’ perspective of their health status and perceived benefit from TAVI. The CCS TAVI Working Group selected the KCCQ and the EQ-5D measured at baseline (time of eligibility assessment) and 12 months after TAVI.

As a starting point, the CCS TAVI Quality Report documents the proportion of patients with QOL measurement at both time points. The goal is to use QOL as an outcome indicator in the future.

Table 1. Evaluation of QOL (CCS Quality Indicator)

| Description                                                                 | The proportion of patients with a comprehensive assessment of health related quality of life incorporating a heart failure-specific measure, KCCQ, and a generic measure, EQ-5D 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 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                                                                                         |

The domains of self-reported health status measured include the following:

![Figure 1. Questionnaires and associated domains of QOL recommended by the CCS TAVI Quality Indicator Working Group](image)

**Kansas City Cardiomyopathy Questionnaire:**
- Summary score
- Physical limitation
- Symptoms
- Quality of life
- Social limitations

**Health Thermometer:**
- Mark an “X” on the scale to indicate how your health is today (0-100)

**EQ-5D**
- Mobility
- Self-care
- Usual activities
- Pain/discomfort
- Anxiety/depression
2. OPPORTUNITIES AND CHALLENGES

The measurement of QOL refers to information obtained directly from patients about a health condition and its management. QOL is measured using validated self-report questionnaires that provide multidimensional measures, including symptoms, function, and physical, mental and social health status. QOL is often used interchangeably with health-related quality of life, patient-reported outcome measurement, and self-reported health status. The inclusion of QOL in registries is increasingly emerging as an important component of a comprehensive outcome evaluation.

The measurement of QOL is an essential component of a patient-centred quality report. This is not unique to TAVI; its inclusion is under consideration and/or at various stages of implementation across the continuum of cardiac care. By selecting this quality indicator, the TAVI Quality Working Group has assumed a leading role in demonstrating their commitment to health system transformation.

The selection of the KCCQ and the EQ-5D is in keeping with the best practice of adopting validated tools that capture both generic health status and disease-specific domains:

![Conceptual model of domains captured in QOL instrument](image)

**Figure 2.** Conceptual model of domains captured in QOL instrument

**Opportunities**

1. **Improved case selection:** Baseline self-reported health status is a predictor of outcome after TAVI

**Structural Heart Disease**

**Association of Patient-Reported Health Status With Long-Term Mortality After Transcatheter Aortic Valve Replacement**

**Report From the STS/ACC TVT Registry**

Suzanne V. Arnold, MD, MHA; John A. Spertus, MD, MPH; Sreekanth Vemulapalli, MD; Dadi Dai, PhD; Sean M. O’Brien, PhD; Suzanne J. Baron, MD, MSc; Ajay J. Kirtane, MD, SM; Michael J. Mack, MD; Philip Green, MD; Matthew R. Reynolds, MD, MSc; John S. Rumsfeld, MD, PhD; David J. Cohen, MD, MSc
2. **Augmentation of outcome and health service evaluation:** Combined with mortality and morbidity, the measurement of QOL enables a comprehensive and patient-centred evaluation framework. QOL data is required to conduct cost-effectiveness evaluation.

![Figure 3. Comprehensive evaluation framework for quality TAVI care](image)

3. **Better reflection of health policy priorities:** Across regions, jurisdictions, and funders, the culture of health care is shifting from disease-centred and provider-focused to patient-centred (see examples below). To this end, the inclusion of QOL as a quality indicator reflects this as a top priority by including the rigorous assessment of patients’ perceived benefit of treatment. Resources, frameworks, and strategic plans of numerous health-focused organizations across the country show evidence of this shift. Specific examples are included below.

“In. Building a culture of patient-centred care

The concept of “patient-centred care” is taking hold in other developed countries which are also in the process of reforming their health care systems. The essential principle is that health care services are provided in a manner that works best for patients. Health care providers partner with patients and their families to identify and satisfy the range of needs and preferences. Health providers, governments and patients each have their own specific roles in creating and moving toward a patient-centred system”.

![Figure 4. Canadian Medical Association: Health Care Transformation in Canada](image)
Challenges

- The primary challenge of QOL measurement is that the patient is the only source of data: self-reported health status can only be measured by asking the patient directly without the interpretation by a clinician or any other person.
- Challenges and barriers include the method of documenting (e.g., paper, electronic solution), patients' level of literacy and language fluency, integration in clinical processes, time requirements, and interpretation/use of data.

3. PRACTICAL TIPS AND BEST PRACTICES

Sites have reported using the following strategies to obtain QOL data:

- Incorporate information about the rationale for measuring QOL in patient education brochure;
- Mail a paper copy with clear instructions to patients at the time of first contact (e.g., with notice of appointment and patient education brochure) and at the time of one year follow-up (Consider obtaining funding for a self-addressed stamped envelope);
- Have paper copies readily available at the time of patients’ clinic visit;
- Obtain versions available in different languages (KCCQ is available in over 25 languages);
- Conduct the assessment by telephone as needed;
- Explore feasibility of an electronic system to collect measurements;
- Develop a QOL report to include in each patient's chart to foster a culture where this data is valued;
- Consider a multidisciplinary team meeting to learn more about scientific approaches to the measurement of patient-reported outcomes and use in clinical practice to build consensus;
- Encourage the inclusion of QOL in program evaluation.
4. QUESTIONS AND ANSWERS

Do the KCCQ and EQ-5D require a license?

Yes. See Resources.

Clinicians say that patients don’t like being asked about their QOL or completing questionnaires. What does the evidence say?

This is not what the evidence shows. In contrast, many patients report high levels of satisfaction when asked questions that reflect their overall experience of treatment and personal values regarding their health. From a patient’s perspective, improved QOL can be a more important outcome than improved quantity of life.

Clinicians say they don’t understand the data and what it means. How can QOL data become a useful clinical report and an accepted component of the CCS TAVI Quality Report?

The following report (dummy data) is produced annually by CSBC to augment the reporting of mortality, morbidity, and hospital readmission. It provides a report of the shift in the KCCQ scores from baseline to post-procedure, and an indication of the count of patients who report a satisfactory QOL (KCCQ>60). This type of report can provide a valid representation of change in QOL that can accompany mortality curves to provide a fulsome appreciation of outcomes.

Figure 6. Sample illustration of changes in QOL in provincial registry using fictional data (Cardiac Services BC)

People say that the reporting of QOL does not change clinicians’ decisions.

Clinicians need to see the data systematically to be able to understand and use it. The reporting of QOL can help inform clinicians’ recommendations and evaluate individual outcomes.

People say that QOL measurement is “pseudoscience”. What does the evidence say?

The measurement of patient-reported outcomes is a well-established and growing area of scientific research. Patient-reported measurements are validated and reliable measures of patients’ self-reported health status. The US Food and Drug Administration (FDA) have mandated the measurement of QOL in clinical trials of many drugs and devices, and recognize that rigorous scientific methods are available to investigators. The collection of QOL data is a requirement for US Medicare funding.

We know QOL improves after TAVI. Why continue with on-going measurement?

Clinician-reported outcomes (e.g., mortality, morbidity, hospital readmission) are well established. Yet, there continues to be a need to report on various outcomes to guide treatment decision and quality of care. QOL data augments clinician-reported outcomes and provides a rigorous assessment of patient’s self-reported health status.
5. RESOURCES

- License for KCCQ
- License for EQSD

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HEART TEAM TREATMENT RECOMMENDATION MODULE

CONTENTS
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MODULE OVERVIEW
In the TAVI Toolkit Heart Team Treatment Recommendation module, users are provided with:
• Objective and key considerations for documenting Heart Team Treatment Recommendation;
• Benefits and challenges of using a Heart Team decision-making approach;
• Practical tips to promote Heart Team decision making; and
• Helpful resources to support implementation.

Following review of this module, users will have strategies and tools to support the documentation of a Heart Team approach to treatment for this structural indicator.
### I. CCS QUALITY INDICATOR DEFINITION

Documentation of Heart Team Treatment Recommendation aims to promote a multi-disciplinary decision-making process to support quality of care.

**Table 1. Heart Team Treatment Recommendation (CCS Quality Indicator)**

<table>
<thead>
<tr>
<th>Description</th>
<th>HEART TEAM TREATMENT RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Numerator</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Denominator</strong></td>
<td>Total number of patients referred for TAVI at a center in a given observation period.</td>
</tr>
<tr>
<td><strong>Method of Calculation</strong></td>
<td>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?)</td>
</tr>
</tbody>
</table>
| **Sources of Data** | Institutional clinical data  
Hospital records (patient charts) |

The Heart Team approach is widely endorsed in international guidelines as a strong recommendation. The primary purpose is to leverage multi-disciplinary expertise to guide the management of patients with complex severe valvular heart disease. A strong, collaborative Heart Team is widely accepted as a requisite component of TAVI programs.

At a minimum, the Heart Team is comprised of an interventional cardiologist and cardiac surgeons who share expertise in the management of complex structural heart disease. The additional contributions of imaging specialists (CT radiology and echocardiology) and nursing, as well as anaesthesiology, heart function specialists, and geriatric cardiology can augment the multi-disciplinary expertise.

A Heart Team approach is well suited to conduct the complex evaluation of patients with heart valve disease. The approach relies on their collective understanding of the risks and benefits of different treatment options to determine if TAVI is indicated, technically feasible, and reasonable. The Heart Team can present treatment options to patients and their family to foster shared decision-making.
Figure 1. CCS Position Statement: Clinical decision trees for patients with AS²
2. OPPORTUNITIES AND CHALLENGES

Opportunities

TAVI owes much of its success to the Heart Team given the integral role they play in this (among other) complex cardiac management programs. This has been attributed to the multi-disciplinary approach the Team takes which prioritizes the interests of clinicians and patients, as well as the advancement of transcatheter heart valve innovation. Patient selection remains a significant challenge, especially as evidence continues to evolve. The goal is for the multidisciplinary team to move away from a system of fragmented care and offer a balanced and complementary approach to guide the management of patients with complex heart valve disease.

The expertise of cardiology and cardiac surgery provides complementary input to build a consensus treatment recommendation for each patient and contribute to individualized procedure planning. In addition, the input of imaging specialists, anaesthesiologists, nurses, geriatric medical specialists and other engaged experts can augment the quality of case selection and the anticipation of procedural and post-procedural needs.

The role of the TAVI nurse coordinator is pivotal to coordinate the complex aspects of patients’ assessment and procedure planning, facilitates effective and streamlined multi-disciplinary collaboration, and serves as a central point of contact for patients and their family. Centres can capitalize on the availability and interest of diverse stakeholders by including them in the multidisciplinary assessment, the treatment recommendation meetings, and the in-hospital care. This “large Heart Team” concept can be an effective approach to implement coordinated and comprehensive strategies along patients’ journey of care from referral to follow-up.

Figure 2. Conceptualization of a “Large” Heart Team approach to care of TAVI patients
Challenges

Canadian centres have reported the following challenges in promoting a Heart Team approach:

- There is no clear consensus on the definition, desired goals, means of implementation, and metrics to assess success and unintended consequences of a Heart Team approach. There is a need to study the hypothesized benefits, understand how the Heart Team improves care, and identify the structural and operational factors that are central to its success. Metrics are required to measure the timeliness and appropriateness of recommendations and outcomes.
- A Heart Team approach requires time and collaboration between stakeholders across disciplines who may not routinely meet. Finding a suitable time to discuss patients and ensuring the key stakeholders are present can be challenging. Overcoming these logistical barriers can be perceived as excessively difficult in spite of the support of the Team.
- There can be uneven buy-in from different disciplines about the value-add of the process. There are few studies reporting evidence about the value of a Heart Team approach.
- If a program is built on a traditional model of referrals to individual cardiologists or surgeons rather than the endorsement and operationalization of a centrally coordinated program, the timing and impact of a Heart Team meeting can be problematic.
- The documentation of the Heart Team’s recommendation is not standardized. It is unclear how the process can help improve TAVI programs and multi-disciplinary communication.

3. PRACTICAL TIPS AND BEST PRACTICES

Using Documentation of Heart Team Recommendations to Improve Communication

The development of a program-endorsed form that serves as a template for recording individual treatment recommendations and provides a preliminary procedure plan that can be a helpful clinical tool.

Data elements that can be helpful include:

- Basic patient demographics, including urgency (e.g., elective out-patient vs. urgent in-patient);
- Treatment recommendations, including reasons patient may not be accepted for TAVI;
- Procedure planning, including planned procedural approach, pre-procedure requirements, etc.;
- Record of Heart Team members present for discussion.

See Resources for examples of forms used in Canadian centers to document Heart Team Recommendations. These forms can be adapted to meet local needs.

Using Documentation of Heart Team Recommendation to Support Shared Decision-Making

As TAVI quality indicators evolve, it will become increasingly important to support patients’ treatment recommendation. Helping patients opt for SAVR or TAVI, or on-going medical management when treatment may not be recommended or would be futile, requires a concerted approach by the Team. To this end, the Heart Team becomes a vehicle to facilitate joint decision-making.

Shared decision-making is a process by which clinicians and patients work together to select treatment based on clinical evidence and the patient’s informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients’ informed preferences. Shared decision-making improves decision quality and patient satisfaction and, in some cases, results in more cost-effective care.
Resources for Clinicians:
The translation of clinical practice guidelines is an important step to facilitate the uptake of evidence in clinical care. International guidelines continue to evolve rapidly to keep pace with clinical trials, new procedural approaches and devices, and a large volume of emerging evidence. In 2016, an international panel of experts considered the evidence of three linked rapid systematic reviews; it produced an interactive set of recommendations for clinicians to consider when making a treatment recommendation.

![Flowchart for management of severe aortic stenosis](image)

**Figure 3.** Flowchart for management of severe aortic stenosis

See Resources for further details.

Resources for Patients:
Decision aids are a part of a shared decision-making process. These tools help people take an active role in decision-making by making explicit the decision that needs to be made, providing information about the options and outcomes, and by clarifying personal values. They are used and presented by clinicians and are a means of helping people make informed choices about healthcare that take into account their personal values and preferences. They are designed to complement, rather than replace, counseling from a health practitioner.

The goals are:
- To inform people about the available options, from an evidence-based perspective
- To encourage active engagement with the decision-making process
- To help people think through what is important to them, so that they can make choices that reflect their own values and preferences
The ACC CardioSmart Decision Aids hub recently expanded to include two new free, downloadable TAVI Decision Aid Tools that help patients understand what AS is and what treatments are available.

The first tool guides patients with intermediate or high surgical risk through the treatment options available for severe AS and helps them choose between TAVI and surgery. The second tool is dedicated to patients with prohibitive surgical risk/patients who are inoperable to help them evaluate the proper treatment and choose between TAVI and symptoms management/palliative approach. See Resources for further details on this ACC resource.

**Incorporating the Measurement of Frailty in the Heart Team Treatment Recommendations**

Careful case selection remains an important component of TAVI program quality. In addition to the pivotal question about whether TAVR is anatomically and clinically feasible, there is strong evidence to support the consideration of patients’ frailty when making individual treatment recommendations and determining patients’ likelihood to derive benefit.

Frailty is different than aging; it is not captured in surgical risk scores and helps explain the heterogeneity of older adults. Frailty is a complex health state, often defined as an age-related, multi-system syndrome that increases health vulnerabilities and risks of adverse events (e.g., significant decline, functional impairment, death) when exposed to stressors (e.g., hospitalization, illness), compared to patients who are the same age.

Frailty may be associated with increased risk of major adverse events including in-hospital complications, longer length of stay, increased hospital readmission, worsening quality of life, falls, functional dependence, disability, and death. The predictive value of frailty was highlighted in early clinical trials and continues to play a role in international administrative registries and on-going studies. The cycle of frailty in cardiovascular disease is well documented:

![Cycle of frailty and cardiovascular disease](image)

**Figure 4. Cycle of frailty and cardiovascular disease**

[4]
Measuring frailty in clinical practice can be challenging to measure consistently and rigorously, and its value is often questioned. Upward of 20 frailty assessment tools have been developed, leading to significant confusion and variability in clinical care and research. The absence of consensus surrounding frailty assessment tools, the unstandardized measurements employed in research and clinical care, and the lack of validation in the TAVI population have been significant barriers to the seamless integration of frailty measurement in practice.

The recent publication of the Essential Frailty Toolset (EFT)5 gives clinicians a pragmatic and reliable tool to measure frailty in TAVI programs. The EFT is a simple assessment of four easily available indicators:

1. Chair rises [Lower extremity strength]: The capacity to perform five sequential chair rises with arms folded on chest. The timer starts when the patient is sitting on a flat chair and instructed to begin to stand; it is stopped when the patient stands at the completion of the last stand.

2. Cognitive status [Short term memory and orientation]: The score obtained on the Mini-Cog™ measurement of three-word registration and clock drawing; alternatively, the following questions can be asked: (1) What day of the month is it? (2) What day of the week is it? (3) What hospital are you in? and (4) What floor are you on?

3. Hemoglobin

4. Albumin

The four indicators generate a score that is associated with a predictive risk of 1-year mortality for TAVI and SAVR. The EFT is quick to perform, does not require specialized equipment, and has high inter-observer reliability; it is available as a free smart phone application and does not require a license.

![Essential Frailty Toolset components and score](image)

**Figure 5.** Essential Frailty Toolset components and score5

If measured, information about frailty should be shared with the Heart Team at the time of treatment recommendation. See Resources for an example of documentation of frailty using the Essential Frailty Toolset.
4. QUESTIONS AND ANSWERS

Does documenting a Heart Team approach mean that both interventional cardiologists and cardiac surgeons must participate in each procedure?

The intent of this structural quality indicator is to promote the participation of both specialists in treatment recommendations. This joint expertise is essential for case selection and procedure planning. The configuration and expertise of implanting medical teams varies across centres and is not captured in this quality indicator.

There is no evidence that a Heart Team approach makes a difference for outcomes in the era of contemporary TAVI. Why should we continue to promote it?

There is widespread endorsement of the rationale for team-based care of complex patients in the rapidly evolving clinical context of transcatheter heart valve therapies. In spite of low levels of evidence, the recommendation for programs to maintain a Heart Team approach remains highly recommended in Canadian and international guidelines.

To comply with the CCS Quality Indicator, do people need to meet in-person to discuss patients, or can the discussion happen in other ways (e.g., telephone, e-mail, remote meetings)?

The spirit of the quality indicator is to favour in-person, focused recommendations that employ multi-modality imaging and promote multi-disciplinary input.

How should results of tests concerning frailty or shared decision-making be used by the Heart Team?

Ideally, the Heart Team conducts a comprehensive assessment inclusive of anatomical and functional (e.g., frailty) criteria, and patient perspective. The TAVI nurse coordinator is well suited to present findings related to the assessment of frailty and report on conversations with patients to highlight their goals of care.
5. RESOURCES

The following resources are provided for reference only and are reflective of local practices and clinical contexts. These examples may not be the most current in use at these sites and are shared to promote quality improvement only.

Resource #1: Documentation of Heart Team Treatment Recommendations for Procedure Planning from Canadian Centres

<table>
<thead>
<tr>
<th>Status:</th>
<th>Elective</th>
<th>In-Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nursing Assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiogram</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documented Surgical Opinion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not required (Patient &gt; 85 or other exemption)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CT Scan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TEE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Assessments Completed (for office use)**

- Nursing Assessment
- Documented Surgical Opinion
- Not required (Patient > 85 or other exemption)
- CT Scan
- TEE

**Treatment Recommendation**

- Patient Status: Elective In-Patient
- Assessments Completed: Nursing Assessment, Angiogram, CT Scan, TEE

**Decision:**

- Accepted for TAVI: TF, TA, Subclavian
- Not Accepted for TAVI: Re-Refer to Surgery, Consider Re-Referral for TAVI

**Risk Stratification**

- Anatomical/Peri-Procedure Risks: Suitable for Cath Lab
  - Adequate femoral artery size and anatomy
  - Social support for next day discharge
- Functional/Post-Procedure Risks: Suitable for Next Day Discharge
  - No anticipated vascular percutaneous access or closure issues
  - No significant mobility issues
  - BMI < 30
- No subannular calcification
- eGFR > 30 ml/min
- Able to follow verbal commands
- Discharge plan
- Other: Other:

**Procedure Planning**

- Planned TF access size: cm²
- X-ray angle:
- Valve eligibility: Eligible for all standard devices
- Eligible for specific device(s) only: Device 1, Device 2, Device 3, Other:
- TF approach: Local anaesthesia/conscious sedation, General anaesthesia, Cath lab, Hybrid OR
- Pre-procedure requirements: None, PCI, Pre-TAVI "go", Single stage, BAV, Other:
- Surgical back-up: Standard consent for TAVI/emergency intervention, Not suitable for heart surgery
- Screen for research:
  - TA approach: Interventional cardiologist required, Cath lab nurse required (e.g., high risk LM occlusion)
  - Surgical back-up: Standard consent for TAVI/emergency intervention, Not suitable for heart surgery
  - Urgency: Standard, Urgent out-patient, Urgent in-patient
- Present for discussion:
  - Blanke, Boone, Cheung, Cook, Leipsic, Ye, Webb, Wood
- Anesthesia, Nursing, Other:
- Other:
- Anticoagulation bridging: Prescribers’ orders completed
- Date:

**Figure 6.** Sample documentation of Heart Team treatment recommendations for procedure planning (Centre for Heart Valve Innovation, St. Paul’s Hospital, Vancouver General Hospital)
**Resource #2: Shared Decision-Making**

Example #1: The following shared decision-making resource is published as a free, open access manuscript. The resource outlines the following statement:

> “Severe aortic stenosis affects approximately 3 in 100 people over the age of 75 years. Patients typically experience symptoms of heart failure and reduced quality of life. Without aortic valve replacement, life expectancy is typically 50% at two years, with escalation of heart failure and reduced quality of life. These recommendations are for patients with symptoms and severe aortic stenosis: patients without symptoms or with milder disease are not considered here.”3

---

**Choice of intervention for those with severe aortic stenosis**

- **Transfemoral TAVI**
  - Inserting a new valve into the aortic valve’s place without open heart surgery; delivery is through the femoral artery.

- **SAVR**
  - Open-heart surgery, to remove the narrowed aortic valve, and replace it with tissue valve.

### Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Favours TAVI</th>
<th>Favours SAVR</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 85+</td>
<td>Strong</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 75–84</td>
<td>Weak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age 65–74</td>
<td>Weak</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age under 65</td>
<td>Strong</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Key uncertainties

The major uncertainty is the durability of TAVI valves which drives recommendations in favour of SAVR in younger patients.

---

**Choice of intervention for people with severe aortic stenosis who are unsuitable for TAVI by transfemoral approach**

- **Transapical TAVI**
  - A more direct delivery of the new valve, through the 6th or 5th intercostal space, into the left ventricle.

- **SAVR**
  - Open-heart surgery, to remove the narrowed aortic valve, and replace it with tissue valve.

### Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Favours TAVI</th>
<th>Favours SAVR</th>
<th>Why?</th>
</tr>
</thead>
<tbody>
<tr>
<td>All ages</td>
<td>Strong</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Figure 7.** Key considerations for patients with symptoms and severe AS."
## Practical Considerations

### TAVI

**Procedure**
- Conscious sedation
- Catheter-based procedure
- Under 2 hours
- Navigator purge the valve and attached to a flexible, mechanical frame

**Recovery**
- Typically 2-3 days in hospital
- About 1 month to recover
- Pain from insertion site resolves within a few weeks
- Data on clinical or wellbeing after TAVI is scarce

**Adverse Effects**
- Endocarditis (about 1% per year)
- Request procedure if unsuccessful
- Some symptoms of heart failure can remain after procedure
- Cognitive decline might occur after valve replacement, but how often is not clear
- Long-term effects of heart is less well known than surgery

**Work & Education**
- Time until return to work depends on speed of recovery
- May be 2-6 weeks

**Travel & Driving**
- Driving may be limited during recovery

**Medication**
- Antplatelet or anticoagulation medication after procedure, as needed
- Pain medication after procedure, as needed

**Visits**
- Post-operative visits are typically within 1-2 months, and then yearly to check that the valve is working

### SAVR

**Procedure**
- General anesthesia
- Major surgery
- About 3-5 hours
- Valve replacement sites becomes a concern issue
- The heart may be stopped and supported by a machine

**Recovery**
- Typically 5-10 days in hospital
- About 2-3 months to recover
- About 3-4 report pain in the sternum after 1 year, with 3 in 10 with more serious pain
- Some report mood swings, anxiety, though may also have been present before surgery

**Adverse Effects**
- See summary of findings

**Work & Education**
- May be 6-8 weeks

**Travel & Driving**
- Driving is limited for 6 weeks until the sternum has heals

**Medication**
- Antplatelet or anticoagulation medication after procedure, as needed
- Pain medication after procedure, as needed

**Visits**
- See summary of findings

---

**Figure 8.** Practical considerations that may influence a patient's choice of procedure.

---

**TOOLKIT: TRANSCATHETER AORTIC VALVE IMPLANTATION**

---

**CANADIAN CARDIOVASCULAR SOCIETY**
Resources #3: Decision Aids
The ACC/CardioSmart has published two decision aids that reflect current evidence. Both brochures call on patients to consider:

- Their goals for treating AS;
- Their concerns related to treatment options;
- Additional questions for their clinician?

1. ACC/CardioSmart decision aid for severe AS treatment options (TAVR vs. Symptom Management)

Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. This booklet is specifically for individuals who cannot have open-heart surgery. You, your family, and your clinicians can begin to discuss which treatment option is best for you”.7 The content focuses on:

(1) Understanding AS;
(2) Treatment options (TAVR vs. symptom management);
(3) Benefits;
(4) Risks; and
(5) Introduction to palliative care.

2. ACC/CardioSmart decision aid for treatment options for severe aortic stenosis for patients deciding between TAVR and surgery

Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. You, your family, and your clinicians can begin to discuss which treatment option is best for you”.8 The following are illustrations of this brochure:

**Figure 9. Understanding AS**

Aortic Stenosis (AS) is tightening of the aortic valve in the heart. This can get worse over time. AS makes it harder for the heart to do its job.

**SYMPTOMS OF SEVERE AS INCLUDE:**
- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.
Every patient is different, and we cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we do about TAVR valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if it ever needs to be replaced.
**THE RISKS & BENEFITS OF YOUR OPTIONS**

**TAVR vs. SAVR: Which is the best decision for me?**


---

**TAVR**

**+ BENEFITS:**
- Helps you live longer
- Helps you feel better
- Less invasive procedure
- Shorter recovery time

Nearly 9 in 10 patients are still living within two years and just over 1 in 10 patients will die.

86% live
14% die

**- RISKS:**
- Nearly 1 in 10 patients suffer from a stroke within 2 years
- Nearly 1 in 10 patients suffer from serious injury to blood vessels
- 2 in 10 need a pacemaker within 2 years

---

**SAVR**

**+ BENEFITS:**
- Helps you live longer
- Helps you feel better
- Over 50 years of experience with procedure

Just over 9 in 10 patients are still living within two years and just over 1 in 10 patients will die.

85% live
15% die

**- RISKS:**
- Nearly 1 in 10 patients suffer from a stroke within 2 years
- Less than 1 in 10 patients suffer from serious injury to blood vessels
- 1 in 10 need a pacemaker within 2 years

---

Both TAVR and SAVR have **POTENTIAL PROCEDURAL RISKS** including:

- Death
- Bleeding
- Stroke
- Heart attack
- Infection
- Blood clots

These risks are different for different patients. Talk to your doctor about your individual risks.

---

**IN SUMMARY:**

- TAVR and SAVR are each effective options for helping your aortic valve
- TAVR is a less invasive procedure
- The risk for needing a pacemaker implanted is higher after TAVR
- More is known about how long mechanical valves last (used in SAVR)

---

*Figure 11. Risks and Benefits of TAVR and SAVR*
Figure 12. TAVR vs. SAVR case study

Option 1: Choose TAVR

- TAVR is less invasive.
- The recovery time is shorter.
- Jane can expect similar results.

Option 2: Choose SAVR

- TAVR is a newer procedure, while SAVR has been around for a long time.
- Jane knows people who have had open-heart surgery.

After talking to her clinician, Jane decided the TAVR procedure was the best option for her. She is concerned her other illnesses will make recovering from open-heart surgery more difficult.
**Resource #4: Clinical documentation to support TAVI case selection using EFT**

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<tr>
<td>Cognition: Clock</td>
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<tr>
<td>Albumin</td>
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<td>Hemoglobin</td>
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<td><strong>EFT Score</strong></td>
<td><strong>1/5</strong></td>
<td>(Predicted 1-yr mortality: 6% - All access)</td>
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**Other Fraility Indicators**

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<td>IADLs</td>
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<td>5-Metre Gait</td>
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**Overall Nursing Recommendation**

Comments: ✔

**Figure 13.** Sample clinical documentation to support TAVI case selection using EFT (Centre for Heart Valve Innovation, St. Paul’s Hospital, Vancouver General Hospital)
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SOURCES


COMMON ABBREVIATIONS

ABI: Ankle Brachial Index
ACS: Acute Coronary Syndrome
AF: Atrial Fibrillation
AS: Aortic Stenosis
AVR: Aortic Valve Replacement
BNP: Brain Natriuretic Peptide
BP: Blood Pressure
CABG: Coronary Artery Bypass Graft
COPD: Chronic Obstructive Pulmonary Disease
CPB: Cardiopulmonary Bypass
CPR: Cardiopulmonary Resuscitation
CT: Computed Tomography
CVA: Cerebrovascular Accident
DBP: Diastolic Blood Pressure
DM: Diabetes Mellitus
EF: Ejection Fraction
EQ-5D: EuroQoL-5
FEV: Forced Expiratory Volume
HR: Heart Rate
IABP: Intra-Aortic Balloon Pump
IV: Intravenous
KCCQ: Kansas City Cardiomyopathy Questionnaire
LAD: Left Anterior Descending Coronary Artery
LM: Left Main Coronary Artery
LVEF: Left Ventricular Ejection Fraction
MI: Myocardial Infarction
MRI: Magnetic Resonance Imaging
PCI: Percutaneous Coronary Intervention
PVCs: Premature Ventricular Contractions
QOL: Quality of Life
RCA: Right Coronary Artery
RF: Renal Failure
RSR: Regular Sinus Rhythm
SAVR: Surgical Aortic Valve Replacement
SBP: Systolic Blood Pressure
TAVI: Transcatheter Aortic Valve Implantation
TAVR: Transcatheter Aortic Valve Replacement
VD: Valve Disease