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# CANADIAN CARDIOVASCULAR SOCIETY
# TOOLKIT: TRANSCATHETER AORTIC VALVE IMPLANTATION

2019

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# THE CANADIAN CARDIOVASCULAR SOCIETY (CCS)
# 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.

# EVALUATION OF PROCEDURAL RISK
## MODULE

## CONTENTS

## 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)[1]

| EVALUATION OF PROCEDURAL RISK | |
| --- | --- |
| Description | 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. |
| 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 |

# 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/performed):
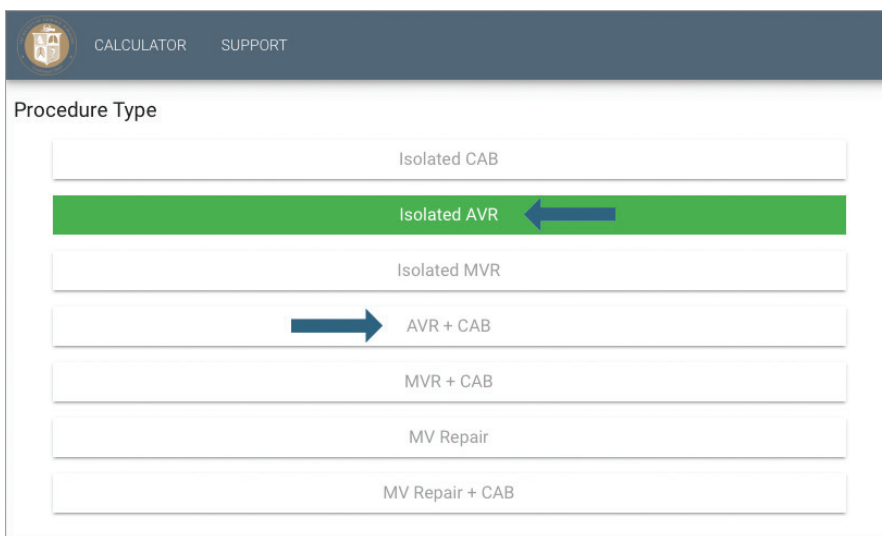


**Figure 1.** Opening View of the STS Online Calculator[2]

## 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[2]

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, immunocompromse, 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.

## LIST OF TABLES

## LIST OF FIGURES

## SOURCES

1. Canadian Cardiovascular Society TAVI Quality Working Group. Quality Indicators E-Catalogue Transcatheter Aortic Valve Implantation. Canada; 2015 September.

2. The Society of Thoracic Surgeons. Online STS Adult Cardiac Surgery Risk Calculator. Available at: http://riskcalc.sts.org/stswebriskcalc/calculate. Accessed on July 28, 2018.

3. The Society of Thoracic Surgeons. STS SCA Data Specifications v2.9 Data Collection Form fields. Available at: http://www.sts.org/sites/default/files/documents/ACSDTrainingManual_V2-9_February2018.pdf. Accessed on July 28, 2018.

# APPENDIX I. STS VARIABLE DEFINITIONS

STS variable definitions have been adapted from the <u>STS manual available online</u>.[3]

| VARIABLE | DEFINITION | COMMENTS |
|---|---|---|
| Hemo Data-EF Done | Measured prior to the induction of anesthesia | EF can be obtained by echo or cardiac catheterization. |
| HF within two weeks | Physician documentation or report of clinical symptoms of heart failure | A low EF alone, without clinical evidence of heart failure, or an elevated BNP without other supporting documentation do not qualify as heart failure. |
| Race Documented | | Race is not routinely collected in Canadian health records used for risk scoring. Not required. |
| RF – Renal Fail-Dialysis | Hemodialysis or peritoneal dialysis | |
| RF – Last Creat Level | Most recent blood creatinine | Convert SI Units (umol/L) to C Units (g/dL) [Normal: 50-110 umol/L or 0.6-1.2 mg/dL]. |
| Cardiac Presentation/ Symptoms (At Time of This Admission) | Angina/ACS at the time of assessment | • Stable: No change in frequency or pattern for six weeks prior to TAVI; <br> • Unstable: Includes one angina at rest, two new onset < 2 months, three increasing angina (intensity, duration, frequency); <br> • 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. |
| Prior MI | Documented previous MI at any time prior to this surgery/TAVI | See training manual for definition of MI <br> Capture time frames: <br> • ≤ 6 hours <br> • > 6 to < 24 hours <br> • 1 to 7 days <br> • 8 to 21 days <br> • > 21 days |
| Cardiac Arrhythmia | History of a cardiac rhythm disturbance | Includes any documented cardiac arrhythmia. |
| AF | History of AF | • Paroxysmal: Spontaneous termination within seven days and most often <48 hours; <br> • Continuous/Persistent: Not self-terminating; lasts longer than 7 days; or prior cardioversion; <br> • None: Currently in normal sinus rhythm. |
| RF – Chronic Lung Disease | Presence and severity of chronic lung disease | • No: No lung disease; <br> • Mild: FEV1 60-75% of predicted, and/or chronic inhaled or oral bronchodilator therapy; <br> • Moderate: FEV1 50-59% of predicted, and/or chronic steroid therapy aimed at lung disease; <br> • Severe: FEV1 < 50% predicted, and/or Room Air $pCO_2$ > 50; <br> • 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); <br> • Unknown: Not known and not documented. |

| VARIABLE | DEFINITION | COMMENTS |
|---|---|---|
| RF – Cerebrovascular Disease | Includes history of:<br>(1) Stroke;<br>(2) Transient ischemic attack;<br>(3) Non-invasive or invasive arterial imaging test demonstrating ≥ 50% stenosis of major cranial vessels; or<br>(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;<br>• Amputation: For arterial vascular insufficiency; vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (does not include vein stripping);<br>• Documented abdominal aortic aneurysm with or without repair;<br>• 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:<br>• Diet only;<br>• Oral agent (with or without diet);<br>• Insulin (any combination with insulin);<br>• Other adjunctive treatment;<br>• None;<br>• Unknown. |
| RF – Hypertension | | Document if:<br>• Diagnosed and treated with medication, diet, and/or exercise; SBP>140 and/or DBP>90 (if no diabetes or chronic kidney disease), or<br>• 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;<br>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:<br>1. Organisms cultured from valve or vegetation; or<br>2. (2) Two or more symptoms (see list) | Choose "Yes" for patients with pre-operative endocarditis who begin antibiotics post-operatively.<br>• Treated: No antibiotic medication (other than prophylactic medication) is being given at the time of surgery;<br>• Active: The patient is currently being treated for endocarditis. |

| VARIABLE | DEFINITION | COMMENTS |
|---|---|---|
| Coronary Anatomy/ Disease known | | 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: <br><br>1. One of LAD system, or Circumflex system, or RCA system with ≥ 50% stenosis; <br><br>2. Two of LAD system, or Circumflex system, or RCA system with ≥ 50% stenosis; or Left Main disease with ≥ 50% stenosis; <br><br>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. <br><br>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. |
| Status | Clinical status prior to surgery/TAVI | Most TAVI patients fall under these categories: <br>• Elective: Out-patient; <br>• Urgent: In-patient. |
| Resuscitation | Cardiopulmonary resuscitation before the start of TAVI (includes CPR at the institution of anesthetic management) | Capture resuscitation timeframe within 1 hour *or* between 1 and 24 hours pre-op. |
| Cardiogenic Shock | Development of cardiogenic shock before undergoing TAVI: > 30 min episode of hypoperfusion (SBP<90 mmHg, CI <2.2 L/min/m2, and/or IV inotropic or vasopressor or mechanical support) | Capture cardiogenic shock timeframe within 1 hour *or* between 1 and 24 hours pre-op. <br>Transient episodes of hypotension reversed with IV fluid or atropine do not constitute cardiogenic shock. |
| Classification – NYHA | Worst dyspnea or functional class, coded as the NYHA classification within the past two weeks | • Class I: No limitations of ADL's. Limiting symptoms may occur with marked exertion; <br>• Class II: Slight limitation of ADL's. Patient is comfortable at rest. Ordinary physical activity results in fatigue, dyspnea and anginal pain; <br>• Class III: Marked limitation of physical activity. Patient comfortable at rest. Less than ordinary physical activity causes fatigue, dyspnea and angina; <br>• 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. |
| IABP | Placed on an IABP | Capture time frame: <br>• Pre-operatively; <br>• Intra- operatively; <br>• Post- operatively. |
| Meds – Inotropes | | Administration of IV inotropic agents within 48 hours preceding surgery/TAVI. |

| VARIABLE | DEFINITION | COMMENTS |
|---|---|---|
| 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.<br>Capture time frame:<br>• ≤ 6 hours;<br>• > 6 hours. |
| VD – Mitral, Aortic, Tricuspid | Presence of valve disease<br>• Mitral: Stenosis and/or Insufficiency<br>• Aortic: Stenosis and/or Insufficiency<br>- Tricuspid: Insufficiency | Capture severity of insufficiency:<br>• Enter level of valve function associated with highest risk (i.e., worst performance);<br>• Enter the highest level recorded in the chart;<br>- '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). |