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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 QUALITY OF LIFE MODULE

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## 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

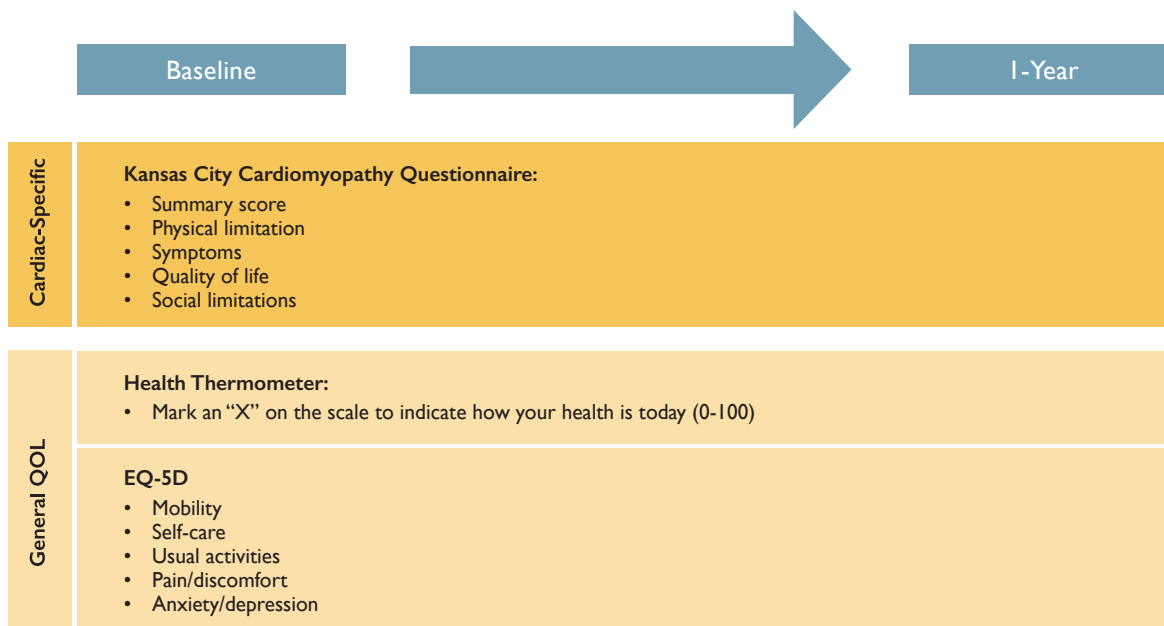
The measurement of QOL quality indicator aims to improve patient selection and augment outcome evaluation by reporting on reliable measurements of patients' perspective of their health status and perceived benefit from TAVI. The CCS TAVI Working Group selected the KCCQ and the EQ-5D measured at baseline (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 I.** Evaluation of QOL (CCS Quality Indicator)<sup>1</sup>

EVALUATION OF QUALITY OF LIFE	
Description	The proportion of patients with a comprehensive assessment of health related quality of life incorporating a heart failure-specific measure, 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:



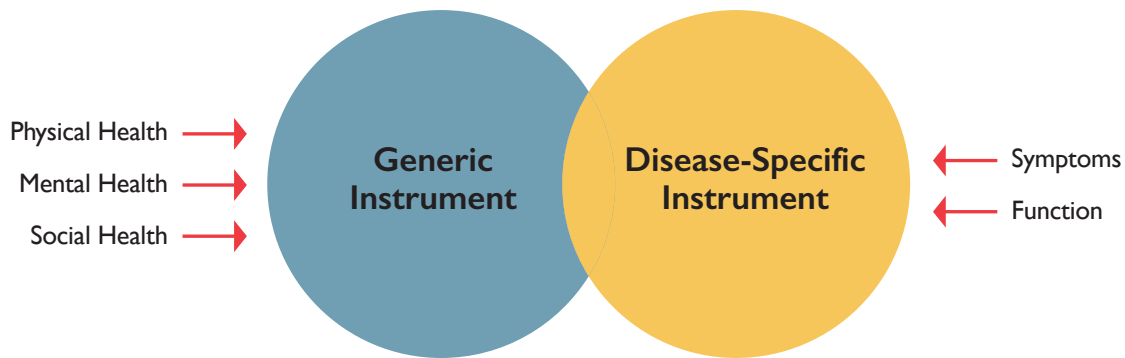
**Figure I.** Questionnaires and associated domains of QOL recommended by the CCS TAVI Quality Indicator Working Group

## 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:



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

### Opportunities

- I. **Improved case selection:** Baseline self-reported health status is a predictor of outcome after TAVI<sup>2</sup>

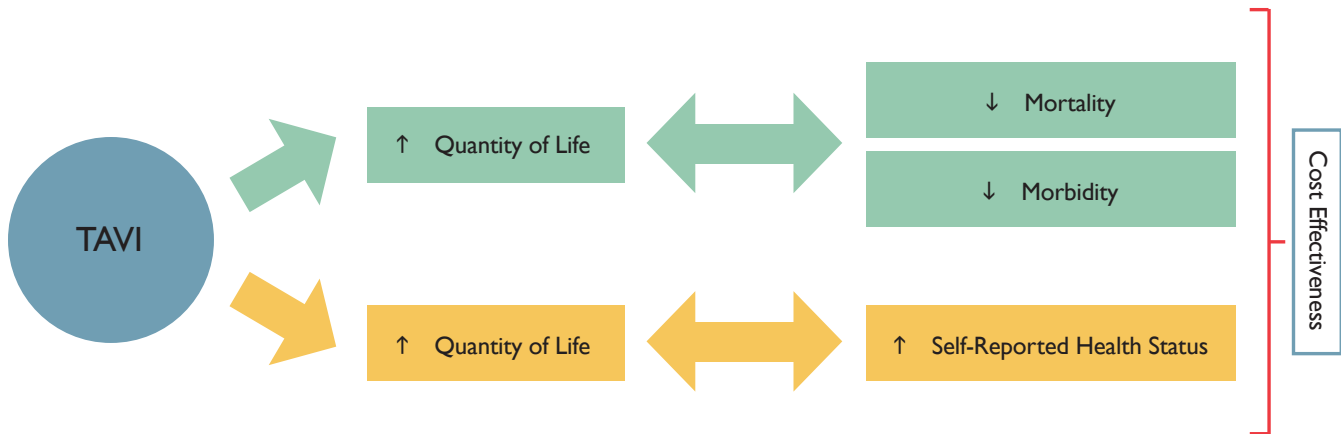
## Structural Heart Disease

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

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

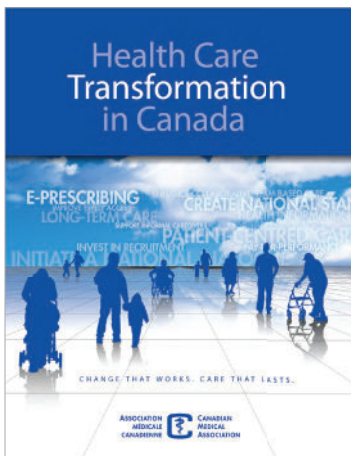
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2. **Augmentation of outcome and health service evaluation:** Combined with mortality and morbidity, the measurement of QOL enables a comprehensive and patient-centred evaluation framework. QOL data is required to conduct cost-effectiveness evaluation.



**Figure 3.** Comprehensive evaluation framework for quality TAVI care

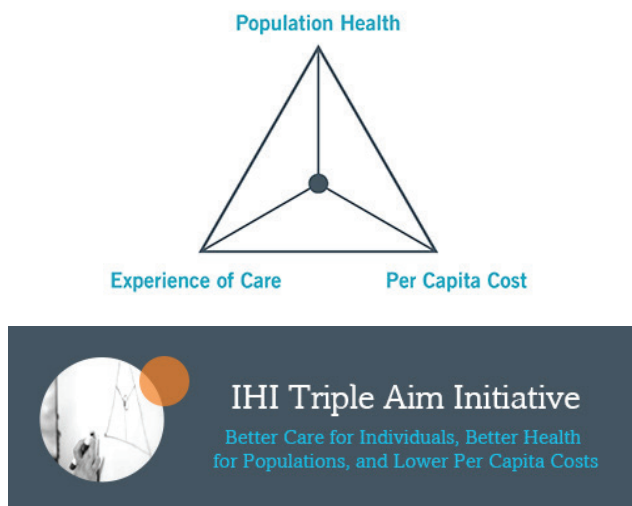
3. **Better reflection of health policy priorities:** Across regions, jurisdictions, and funders, the culture of health care is shifting from disease-centred and provider-focused to patient-centred (see examples below). To this end, the inclusion of QOL as a quality indicator reflects this as a top priority 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.



**“1. 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”.*<sup>3</sup>

**Figure 4.** Canadian Medical Association: Health Care Transformation in Canada<sup>3</sup>

## The IHI Triple Aim



**Figure 5.** Institute for Healthcare Improvement Triple Aim Framework<sup>4</sup>

### 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.

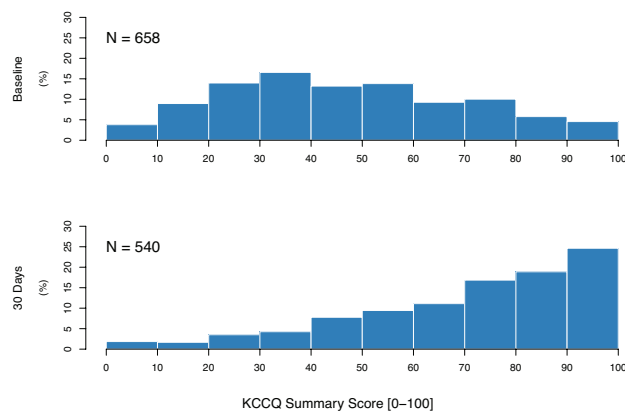
*Clinicians say they don't understand the data and what it means. How can QOL data become a useful clinical report and an accepted component of the CCS TAVI Quality Report?*

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.



**Distribution of KCCQ Summary Score**

Transfemoral TAVI (Jan 1 2015 – May 31 2017)



**Figure 6.** Sample illustration of changes in QOL in provincial registry using fictional data (Cardiac Services BC)<sup>5</sup>

*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 EQ5D](#)

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## SOURCES

1. Canadian Cardiovascular Society TAVI Quality Working Group. Quality Indicators E-Catalogue Transcatheter Aortic Valve Implantation. Canada; 2015 September.
2. Arnold SV, Spertus JA, Vemulapalli S, Dai D, O'Brien SM, Baron SJ, et al. Association of patient-reported health status with long-term mortality after transcatheter aortic valve replacement: report from the STS/ACC TVT Registry. *Circulation: Cardiovascular Interventions*. 2015;8(12):p.e002875.
3. Canadian Medical Association. Health Care Transformation in Canada. Available at: <http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PDI0-05.PDF>. Accessed on July 28, 2018.
4. Institute for Healthcare Improvement. IHI Triple Aim Initiative. Available at: <http://www.ihl.org/>. Accessed on November 30, 2018.
5. Cardiac Services BC. Sample illustration of changes in QOL in provincial registry using fictional data (Cardiac Services BC). Available through <http://www.cardiacbc.ca/>. Accessed on October 11, 2018.