

Quality-Based Procedures Clinical Handbook for Aortic Valve Disease

Cardiac Care Network of Ontario &
Ministry of Health and Long-Term Care

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Quality-Based Procedures Clinical Handbook: Aortic Valve Disease

1.0 Purpose

This Clinical Handbook has been created to serve as a compendium of the evidence-based rationale and clinical consensus driving the development of the policy framework and implementation approach for the Aortic Valve Disease (AVD) Quality-Based Procedure (QBP).

The Cardiac Care Network of Ontario (CCN) serves as a system support to the Ministry of Health and Long-Term Care (the Ministry), Local Health Integration Networks (LHIN), hospitals, and care providers dedicated to improving quality, efficiency, access and equity in the delivery of the continuum of cardiac services in Ontario. CCN's priority is to ensure the highest quality of cardiovascular care, based on evidence, standards and guidelines, and actively monitors access, volumes and outcomes of advanced cardiac procedures in Ontario. In addition, CCN works collaboratively with provincial and national organizations to share ideas and resources and co-develop strategies that enhance and support the continuum of cardiovascular care, including prevention, rehabilitation and end-of-life care.

Working with key stakeholders, CCN helps to plan, coordinate, implement and evaluate cardiovascular care and is responsible for the Ontario Cardiac Registry. The information collected in the Cardiac Registry includes wait time information as well as specific clinical parameters required to evaluate key components of care and determine risk-adjusted outcomes. Through scientific evidence, expert panels and working groups, CCN uses evidence and consensus driven methods to identify best practice and strategies to effectively deliver cardiovascular services, across the continuum of care.

The CCN and a working group of clinical, technical and health data experts and other stakeholders have played an integral role in the planning and development of this QBP.

This document has been prepared for informational purposes only. This document does not mandate health care providers to provide services in accordance with the recommendations included herein. The recommendations included in this document are not intended to take the place of the professional skill and judgment of health care providers.

2.0 Introduction

The Ministry of Health and Long-Term Care (Ministry) established Health System Funding Reform (HSFR) in Ontario in 2012 with a goal to develop and implement a strategic funding system that promotes the delivery of quality health care services across the continuum of care, and is driven by evidence and efficiency. HSFR is based on the key principles of quality, sustainability, access, and integration, and aligns with the four core principles of the ***Excellent Care for All Act*** (ECFAA):

- Care is organized around the person to support their health;
- Quality and its continuous improvement is a critical goal across the health system;
- Quality of care is supported by the best evidence and standards of care; and
- Payment, policy, and planning support quality and efficient use of resources.

Since its inception in April 2012, the Ministry has shifted much of Ontario's health care system funding away from the current global funding allocation (currently representing a large portion of funding) towards a funding model that is founded on payments for health care based on best clinical evidence-informed practices.

Principles of ECFAA have been further reinforced first by Ontario's Action Plan for Healthcare in January 2012, and recently with Patients First: Action Plan for Healthcare in February 2015, which signals positive transformational activity which will require adaptive responses across sectors and organizational levels at a time of accelerated change. The Ministry's commitment is to make Ontario the best healthcare system in the world.

The 2012 Action Plan identified HSFR as a lever to advance quality and ensure that the right care gets provided at the right place and at the right time. HSFR focuses on delivering better quality care and maintaining the sustainability of Ontario's universal public health care system. Ontario is shifting the focus of its health care system away from one that has primarily been health care provider-focused, to one that is patient-centred. The 2015 Action Plan continues to put patients at the heart of the health care system by being more transparent and more accountable to provide health care in a way that maximizes both quality and value.

HSFR comprises 2 key components:

1. Organizational-level funding, which will be allocated as base funding using the Health-Based Allocation Model (HBAM); and
2. Quality-Based Procedure (QBP) funding, which will be allocated for targeted activities based on a "(price x volume) + quality" approach premised on evidence-based practices and clinical and administrative data.

2.1 'Money follows the patient'

Prior to the introduction of HSFR, a significant proportion of hospital funding was allocated through a global funding approach, with specific funding for select provincial programs, wait times services and other targeted activities. However, a global funding approach may not account for complexity of patients, service levels and costs, and may reduce incentives to adopt clinical best practices that result in improved patient outcomes in a cost-effective manner. These variations in patient care evident in the global funding approach warranted the move towards a system where 'money follows the patient'.

Under HSFR, provider funding is based on: the types and quantities of patients providers treat, the services they deliver, the quality of care delivered, and patient experience/outcomes. Specifically, QBPs incent to health care providers to become more efficient and effective in their patient management by accepting and adopting clinical best practices that ensure Ontarians get the right care, at the right time and in the right place.

QBPs were initially implemented in the acute care sector, but as implementation evolves, they are being expanded across the continuum of care, including into the community home care sector, in order to address the varying needs of different patient populations.

Internationally, similar models have been implemented since 1983. While Ontario is one of the last leading jurisdictions to move down this path, this positions the province uniquely to learn from international best practices and pitfalls, in order to create a sustainable, efficient and effective funding model that is best suited for the province and the people of Ontario.

2.2 What are Quality-Based Procedures?

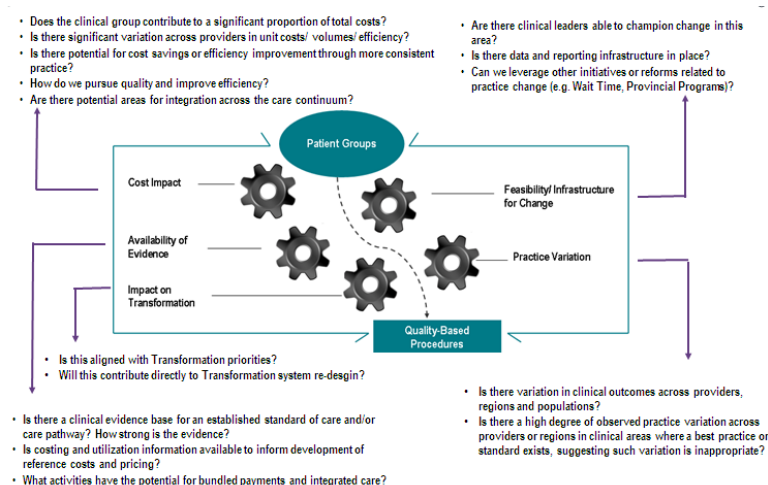
QBPs are clusters of patients with clinically related diagnoses or treatments that have been identified using an evidence-based framework as providing opportunity for process improvements, clinical re-design, improved patient outcomes, enhanced patient experience, and potential health system cost savings.

Initially developed in the acute (hospital) sector, QBPs were defined as “procedures.” However, as implementation evolved since the introduction of QBPs in 2012, so too has the approach. Currently, the expanded focus is on care provided in other parts of the health care sector with a focus on a more functional/programmatic/population-based approach. As a result, the definition of QBPs is expanding to include Quality-Based Procedures, Programs and Populations.

QBPs have been selected using an evidence-based framework. The framework uses data from various sources such as, but not limited to: the Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) adapted by the ministry for its HBAM repository. The HBAM Inpatient Grouper (HIG) groups inpatients based on the diagnosis or treatment responsible for the majority of their patient stay. Additional data has been used from the Ontario Case Costing Initiative (OCCI), and Ontario Cost Distribution Methodology (OCDM). Evidence published in literature from Canada and international jurisdictions, as well as World Health Organization reports, have also assisted with the definition of patient clusters and the assessment of potential opportunities (e.g. reducing variation, improving patient outcomes, sustainability).

The evidence-based framework assesses patients using five perspectives, as presented in Figure 1. It is this evidence-based framework that has identified QBPs that have the potential to improve quality of care, standardize care delivery across the province and show increased cost efficiency.

Figure 1: Evidence-Based Framework



2.2.1 Practice Variation

Practice variation is the cornerstone of the QBP evidence-based framework. A demonstrated large practice or outcome variance across providers or regions in clinical areas, where a best practice or standard exists, represents a significant opportunity to improve patient outcomes through focusing on the delivery of standardized, evidence-informed practices. A large number of 'Beyond Expected Length of Stay' and a large standard deviation for length of stay and costs were flags to such variation.

2.2.2 Availability of Evidence

A significant amount of research has been conducted and collected, both nationally and internationally, to help develop and guide clinical practice. Working with clinical experts, best practice guidelines and clinical pathways can be developed for QBPs and establish appropriate evidence-informed indicators. These indicators can be used to measure the quality of care and help identify areas for improvement at the provider level, and to monitor and evaluate the impact of QBP implementation.

2.2.3 Feasibility/ Infrastructure for Change

Clinical leaders play an integral role in this process. Their knowledge of the identified patient populations, and the care currently provided and/or required for these patients, represents an invaluable element in the assessment of much needed clinical delivery and clinical process improvements. Many groups of clinicians have already developed care pathways to create evidence-informed practice. There is now an opportunity for this knowledge to be transferred provincially.

2.2.4 Cost Impact

The provincial footprint from a financial perspective also impacts the selection of the QBP. This may include QBPs that are high volume and low-cost, as well as those that are low-volume and high costs (i.e. specialized procedures that demonstrate opportunity for improvement).

A selected QBP should have, as a guide, no less than 1,000 cases per year in Ontario and represent at least one percent of the provincial direct cost budget. For patient cohorts that fall below these thresholds, the

resource requirements to implement a QBP can be restrictive. Even where the patient cohorts represent an opportunity for improvement, it may not be feasible, even if there are some cost efficiencies, to create a QBP.

2.2.5 Impact on Transformation

The **Action Plan for Health Care** was launched in January 2012 and is already making a difference to Ontarians and our health care system:

- We've bent the cost curve since 2011/12
- We're improving the health of Ontarians
- We're enhancing the experience of Ontarians when they use the health system
- We're working with our health sector partners to improve the quality of health care

The next phase of Transformation will build on and deepen implementation of the Action Plan. HSFR is a key element of the Health System Transformation Agenda by ensuring sustainability and quality.

Selected QBPs should, where possible, align with the government's transformational priorities. In addition, the impact on transformation of certain patient populations hitherto not prioritized by the framework can be included as QBPs. This will ensure that QBPs are wide ranging in their scope e.g. paediatric patient populations or patients requiring community care. QBPs with a lesser cost impact but a large impact on the provincial health care system may still be a high priority for creation and implementation.

2.3 How will QBPs encourage the delivery of high quality, evidence-based care and innovation in health care delivery?

The QBP methodology is driven by clinical evidence and best practice recommendations from the Clinical Expert Advisory Groups (Advisory Groups). Advisory Groups are comprised of cross-sectoral, multi-geographic and multi-disciplinary membership, including representation from patients. Members leverage their clinical experience and knowledge to define the patient populations and recommend best practices.

Once defined, these best practice recommendations are used to understand required resource utilization for QBPs and will further assist in the development of evidence-informed prices. The development of evidence-informed pricing for the QBPs is intended to incent health care providers to adopt best practices in their care delivery models, maximize their efficiency and effectiveness, and engage in process improvements and/or clinical re-design to improve patient outcomes.

Best practice development for QBPs is intended to promote standardization of care by reducing inappropriate or unexplained variation and ensuring that patients get the right care, at the right place and at the right time. Best practice standards will encourage health service providers to ensure that appropriate resources are focused on the most clinically and cost-effective approaches.

QBPs create opportunities for health system transformation where evidence-informed prices can be used as a financial lever to incent providers to:

- Adopt best practice standards;
- Re-engineer their clinical processes to improve patient outcomes;
- Improve coding and costing practices; and
- Develop innovative care delivery models to enhance the experience of patients.

An integral part of the enhanced focus on quality patient care is the development of indicators to allow for the evaluation and monitoring of actual practice and support on-going quality improvement.

In addition, the introduction of additional QBP's such as outpatient and community-based QBP's will further help integrate care across sectors and encourage evidence-based care across the continuum.

3.0 Description of Aortic Valve Disease

AVD is a cardiac condition in which the aortic valves are malfunctioning causing an obstruction to the flow of blood (stenosis), leakage backward (regurgitation), or both. AVD is caused by a variety of factors and conditions including aging, congenital abnormality, calcification, infection, coronary artery disease, hypertension, etc. The diagnosis and treatment of AVD is important to prevent debilitating sequelae such as heart failure, and sometimes sudden death.

The most frequent valve disease in North America and Europe is currently aortic stenosis (AS), which is most often seen in elderly patients with comorbidities. The most common cause of valvular AS in adults is calcification of a normal trileaflet, or congenital bicuspid valve. Calcific AS is characterized by lipid accumulation, inflammation, fibrosis, and calcification. It typically presents in older individuals (i.e. >75 years) in contrast to bicuspid AS, which presents a decade or so earlier.

The hospitalization rate of valve disease increases with age, with the highest rate of valve disease occurring in men and women between the ages of 69-85.¹ In Ontario, CCN data for fiscal year 2012-13 shows that over 60% of patients who underwent aortic valve surgery (surgical and percutaneous) were 65 years or older. See Table 1 for more details regarding characteristics of AVD patients who underwent isolated surgical aortic valve replacement (SAVR), SAVR with coronary artery bypass graft (CABG), and transcatheter aortic valve implantation (TAVI).

¹ (Cardiac Care Network of Ontario (CCN), 2013)

Table 1: Characteristics of AVD Patients who underwent Advanced Cardiac Procedures in Ontario (FY 12/13)

Characteristics of AVD Patients			
Variables	Isolated AVR	AVR + CABG	TAVI
Volume	985	842	335
Average Age (mean)	67.9	74.1	82.5
Age Cohort (%)			
i) 20 - 44	4.4		
ii) 45 - 64	31.0	14.7	2.4
iii) 65 - 74	29.3	30.4	11.3
iv) 75+	35.3	54.9	86.3
Clinical Baseline Characteristics (%)			
a) Dialysis: (Missing : No : Yes)	2.2 : 96.1 : 1.6	0.2 : 97.6 : 2.1	0.3 : 98.8 : 0.9
b) Diabetes Mellitus: (Missing : No : Yes)	1.8 : 73.1 : 25.1	0.1 : 64.3 : 35.6	0.3 : 63.3 : 36.4
c) Hypertension: (Missing : No : Yes)	2.2 : 34.5 : 63.2	1.2 : 22.3 : 76.5	0.3 : 15.5 : 84.2
d) Hyperlipidemia: (Missing : No : Yes)	2.4 : 46.9 : 50.7	1.9 : 26.7 : 71.4	0.9 : 27.8 : 71.3
e) History of Myocardial Infarction: (Missing : No : Yes)	0.9 : 94 : 5.1	1 : 84.7 : 14.4	0.6 : 76.4 : 23
f) Recent Myocardial Infarction: (Missing : No : Yes)	1.9 : 94.5 : 3.6	0.8 : 83.5 : 15.7	1.8 : 94.6 : 3.6
g) Chronic Obstructive Pulmonary Disease (COPD):			
i) Missing	3.1	0.6	0.6
ii) No	87.3	88.8	80.9
iii) Unknown	0.3	0.4	0.3
iv) Yes	9.2	10.2	18.2
h) History of Smoking:			
i) Current	12.3	11.3	9.3
ii) Former	31.5	41.9	36.4
iii) Missing	2.2	1.4	0.6
iv) Never	53.5	44.9	52.8
v) Unknown	0.5	0.5	0.9
i) Congestive Heart Failure (CHF):			
i) Missing	3.2	0.7	0.6
ii) No	76.6	79.0	47.2
iii) Unknown	0.4		
iv) Yes	19.7	20.3	52.2
j) Cerebral Vascular Disease (CVD):			
i) Missing	3.6	0.5	0.6
ii) No	88.6	86.6	73.7
iii) Unknown	0.4	0.6	6.6
iv) Yes	7.4	12.4	19.1
k) Peripheral Vascular Disease (PVD):			
i) Missing	3.8	3.2	0.6
ii) No	90.8	80.6	77.0
iii) Unknown	0.2	0.5	0.3
iv) Yes	5.3	15.7	22.1
l) Creatinine:			
i) 0 - 120 umol/L	81.7	77.7	52.8
ii) 120-180 umol/L	8.3	11.9	15.5
iii) >180 umol/L	2.7	4.8	7.5
iv) Missing	7.2	5.7	24.2
n) Body Mass Index (BMI):			
i) Underweight	0.5	0.8	1.5
ii) Normal weight	20.8	20.1	22.4
iii) Overweight	34.0	36.1	34.3
iv) Obesity	37.1	36.9	20.6
v) Missing	7.6	6.1	21.2

Data Source: CCN Cardiac Registry

Pathophysiology and Clinical Course

In adults with valvular AS, the obstruction develops gradually, typically over many years during which time the left ventricle (LV) adapts to the systolic pressure overload with progressive concentric hypertrophy. The hypertrophy results in diastolic dysfunction, reduced coronary reserve, myocardial ischemia, and eventually, depressed contractility resulting in LV systolic dysfunction. Typically, patients with AS are free from cardiovascular symptoms (i.e. angina, syncope, and heart failure) until late in the course of the disease.

Once symptoms manifest however, the prognosis is poor with the interval from the onset of symptoms to the time of death being approximately 2 years in patients with heart failure, 3 years in those with syncope, and 5 years in those with angina. Leon et al. reported that among symptomatic patients with moderate to severe AS treated medically, mortality rates after the onset of symptoms were approximately 25% at 1 year and 50% at 2 years, with approximately 50% of deaths being sudden. In the elderly high-risk patients in the Placement of Aortic Transcatheter Valve (PARTNER) - Cohort B trial who were treated medically, the survival at 1 year was only 50%.²

Treatment Option

SAVR is the only effective treatment considered a Class I recommendation by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and European Society of Cardiology (ESC) guidelines in adults with severe symptomatic AS. SAVR has a low operative mortality and satisfactory long term results, even in elderly patients. However, the risk of surgery may be higher in elderly patients with multiple comorbidities. Results from the Euro Heart Survey indicated that 33% of patients with severe valve disease and severe symptoms were not considered for surgery.³

3.1 Alternatives to Surgical Aortic Valve Surgery

3.1.1 Medical Therapy

There are no proven medical treatments to prevent or delay the disease process in the aortic valve leaflets. The overall goal of medical therapy is to treat coexisting cardiovascular conditions and superimposed diseases that often exacerbate the disease process. Even with optimal care, adults with severe symptomatic inoperable AS will have exacerbations of symptoms and frequent hospitalizations. Longer-term palliative medical management of symptomatic AS may be appropriate for patients who are either not candidates for aortic valve surgery due to comorbidities or in patients who decline SAVR.

3.1.2 Balloon Aortic Valvuloplasty (BAV)

BAV was considered to be a less invasive and safe alternative to SAVR, particularly in high surgical risk patients with multiple medical comorbidities. BAV is currently commonly used to stabilize patients while waiting for TAVI procedure. Although BAV results in immediate hemodynamic improvement with a significant decrease in transvalvular gradients resulting in larger valve area, it does not result in sustained clinical improvement. After BAV, high recurrence rates with restenosis or recoil of the aortic valve usually occurs within 6 months. Patients treated with BAV alone have shown poor prognosis, with survival rates of 50% at 1

² (Leon, et al., 2010)

³ (Vahanian, et al., 2012)

year, 35% at 2 years, and 20% at 3 years. BAV, therefore, should not be used as a substitute for SAVR in patients who are candidates for SAVR.⁴

3.1.3 Transcatheter Aortic Valve Implantation (TAVI)

Given the increased mortality and morbidity of SAVR for high-risk patients and the poor long-term results of medical therapy and BAV, an alternative treatment was developed that allows the aortic valve to be inserted percutaneously. A relatively new treatment, TAVI is available to replace the aortic valve without open heart surgery for patients deemed to be too high-risk for conventional surgery. TAVI is a catheter-based procedure using a minimally-invasive approach to replace the diseased aortic valve.

3.2 AVD QBP Definition

This QBP is for the provision of SAVR, SAVR with CABG, and TAVI for the surgical and percutaneous replacement of the aortic valve in patients with AVD. Isolated SAVR is performed when there is no concomitant surgery required (e.g., other valve surgery). Patients with coronary disease undergoing SAVR may be considered for combined SAVR and CABG. The majority of AVD patients will undergo SAVR; however, patients who are considered complex and are at higher risk for surgical treatment may be considered for TAVI as determined by the heart team. Hemodynamically compromised AVD patients are assessed and treated as inpatients while stable AVD patients are scheduled for elective surgery or procedure.

Limitations of Using CIHI Definitions

Two versions of the Cardiac QBP definitions were developed: one utilizes the CCN Cardiac Registry as the data source, and the other uses the CIHI DAD and NACRS. Both sets of definitions were considered for QBP implementation; however, there are fundamental differences between the CIHI and CCN definitions that do not accommodate direct comparisons and lead to discrepancies in volumes.

The CCN definitions have been refined to better reflect homogenous patient cohorts for the Cardiac QBPs to ensure the ability to identify a greater proportion of patients with AVD. These revised definitions are a more accurate representation of the general AVD patient population. Based on the analyses, the Cardiac QBP Advisory Panel recommends that the CCN Cardiac Registry data be used to define procedure volumes.

3.2.1 Overlap with Other QBPs

There is no overlap between the AVD and congestive heart failure (CHF)/chronic obstructive pulmonary disease (COPD) QBPs.

All AVD cases will have a major clinical category (MCC) partition of “I”, which excludes them from the CHF and COPD QBP cohorts.

3.2.2 AVD Inclusion Criteria:

- Patients ≥20 years of age on the date of procedure;
- Ontario-funded cases;

⁴ (Holmes, et al., 2012)

- Patients whose *isolated SAVR*, *SAVR with CABG*, or *TAVI* procedure started.

3.2.3 AVD Exclusion Criteria:

- Cases with an invalid discharge date;
- Outpatient cases; and
- TAVI valves implanted in sites other than the aortic valve.

When there are two or more procedures within a single admission, the case will only fall under only one procedure group, according to the following hierarchy. If an AVD patient also has a CAD procedure within the same admission, the encounter will count as an AVD QBP.



For example, if a patient had an isolated SAVR and then later a TAVI within the same admission, only the TAVI will be included.

See *Appendix B – CCN Cardiac Registry Codes* for the full technical definitions.

3.3 Rationale for choosing AVD as a QBP

Surgical treatment of AVD has been identified as a QBP using the evidence-based selection framework as presented in Figure 4.

Figure 1: Evidence-based framework for AVD QBP

Cost Impact

- In fiscal year 2012-13, there were 985 surgical AVR, 842 SAVR with CABG and 335 TAVI procedures performed in Ontario at significant cost to the healthcare system in the province.

Feasibility/Infrastructure for Change

- There are clinical leaders in cardiac care who are willing to act as champions for positive change.
- Many of these clinical leaders serve as clinical expert members on CCN's clinical working groups.
- CCN has an existing infrastructure and existing relationships with cardiac care providers who participate in the CCN Cardiac Registry.
- CCN has MOHLTC support to maintain the CCN Cardiac Registry.
- The CCN Cardiac Registry is a repository of all cardiac procedures and surgeries performed in Ontario. Following implementation of the QBP-based funding model, the CCN Cardiac Registry will provide a reporting mechanism for advanced cardiac centres to the MOHLTC.
- In October 2012, CCN released an outcomes report for AVR and AVR+ CABG surgery. TAVI outcomes were reported to the MOHLTC and to the individual TAVI programs in 2011.



Availability of Evidence

- 2014 ACCF/AHA Guideline for the Management of Patients with Valvular Heart Disease
- 2013 STS Aortic Valve and Ascending Aorta Guidelines for Management and Quality Measures
- 2012 Transcatheter Aortic Valve Implantation: A Canadian Cardiovascular Society Position Statement
- 2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement
- 2012 Multi-society (AATS, ACCF, SCAI, and STS) Expert Consensus Statement: Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement, Part 1: Transcatheter Aortic Valve Replacement
- 2011 ACCF/AHA Guide line for Coronary Artery Bypass Graft Surgery
- "Report on Adult Cardiac Surgery in Ontario" released by CCN in October 2012
- "Cardiac Care Network Annual Report 2012-2013" released by CCN
- CCN Cardiac Registry, CIHI-DAD and NACRS, OCCl as sources for case costing, unit pricing and clinical data utilization

Practice Variation

- In Ontario, there are 11 cardiac surgery programs capable of performing AV surgeries. Ten of those 11 cardiac centres also have a TAVI program.
- Currently 9 LHINs offer cardiac surgery and 8 offer a TAVI program.
- Mortality rates following isolated SAVR in Ontario are relatively consistent between cardiac centres.
- The provincial average total length of stay (LOS) following isolated AVR surgery, (October 1, 2010 to September 20, 2011), was 8.89 days. The average LOS following isolated AVR surgery for individual cardiac centres ranged from 7.51 to 10.07 days indicating some variation between centres.
- There is also wide variation in the use of blood product transfusions during isolated SAVR. The provincial average rate of red blood cell transfusions was 45% but varied from 17.86% to 59.17% between cardiac centres. The provincial average for plasma or platelet transfusion was 22.35% which ranged from 11.66% to 35.78% between centres.
- Readmission rate for congestive heart failure following SAVR was also quite variable between cardiac centres. The provincial 1 year readmission rate average was 4.74%; however, this rate ranged from 1.29% to 7% between centres.

3.4 Application of the evidence-based framework

3.4.1 Wait Times

CCN collects wait time data for both SAVR and for TAVI in the CCN Cardiac Registry. Wait times data is an important indicator of patterns of patient access to advanced cardiac services. Although a recommended maximum wait time (RMWT) for TAVI procedures does not currently exist, wait times for TAVI patients are reported by 90th percentile (days) and median number of days waiting in the CCN hospital and provincial monthly reports.

As a result, the implementation of wait time monitoring and reporting can conceivably be implemented as part of the evidence-based framework application. Initially, an algorithm based on clinical data, outcomes, and expert opinion, will need to be developed to rank patients. Recommended wait times will also need to be developed to determine best practices in respect to valve disease wait times.

3.4.2 Risk-Adjusted Clinical Outcomes

To examine variations in clinical outcomes across cardiac centres, CCN routinely reports on risk-adjusted post procedural outcomes following advanced cardiac procedures. Recently, CCN started reporting on outcomes following SAVR.⁵ TAVI outcomes have also been calculated however, not reported publicly. For SAVR, risk-adjustment models were available and a comparison of mortality rates between cardiac centres was made. Overall, it was found that mortality rates for SAVR were low, consistent between centres and comparable to other jurisdictions. TAVI mortality rates were also recently calculated and provincial aggregate mortality rates were found to be comparable to published mortality rates from the PARTNER trials^{6 7}. As risk-adjustment models have not yet been developed for TAVI in Ontario, a comparison between centres has not been made. The table below summarizes provincial risk-adjusted mortality from CCN's most recent outcomes reports:

⁵ (Cardiac Care Network of Ontario (CCN), 2012)

⁶ (Leon, et al., 2010)

⁷ PARTNER trial (Placement of AoRtic TraNscathetER Valves) was the world's first prospective, randomized and controlled trial to evaluate the effectiveness of TAVI.

Table 2: Summary of Crude Unadjusted Provincial Mortality Rates Following SAVR and TAVI in Ontario

	SAVR		TAVI	
Mortality Rate	Dates	Rate	Year	Rate
In-Hospital Mortality	October 1, 2008	2.34%	ND	ND
30-Day Mortality	to September 31, 2011	2.03%	January 18, 2007	7.5%
1-Year Mortality	ND	ND	to March 23, 2012	20.5%
2-Year Mortality	ND	ND		26.7%

Data source: In-Hospital Mortality data is calculated by linking CCN Cardiac Registry data to CIHI-DAD data; 30-Day, 1-Year, and 2-Year Mortality data is calculated by linking CCN Cardiac Registry to RPDB data.

The AVD QBP provides the opportunity to standardize adult cardiac care across Ontario. Moreover, it provides opportunities to ensure patients receive the best possible care and achieve optimal outcomes. Quality improvement requires the ability to define the quality indicators to be measured, develop a platform for measurement, and track measured indicators for change. Through CCN's outcomes reports, there already exists a framework of quality indicators with which to measure the quality of adult cardiac care in Ontario and through the CCN Cardiac Registry there already exists a data source from which to calculate these quality indicators. In order to calculate outcomes for SAVR and TAVI, the CCN Cardiac Registry has linked its data to administrative data sources. There are currently a number of quality indicators that CCN has developed to measure the quality of these two cardiac procedures. Currently risk-adjustment models exist for SAVR but will need to be developed for TAVI. CCN will continue to develop and refine quality indicators and risk-adjustment models to measure the quality of these procedures in Ontario and to ensure that Ontarians have access to the highest possible quality of cardiac care.

3.5 Objectives of the AVD QBP

The key objectives of the AVD QBP are to:

- Improve health outcomes of AVD patients;
- Identify and manage the cost of cardiac procedures for the treatment of AVD on the healthcare system;
- Ensure SAVR and TAVI, and related tests are performed appropriately according to recommended guidelines;
- Be accountable to patients with AVD through public reporting of quality and performance metrics;
- Ensure equitable access to standardized care for the SAVR and TAVI treatment of AVD across Ontario; and
- Address service gaps and/or need for capacity and infrastructure management to determine future development needs.

3.6 Documentation and Clinician Engagement

3.6.1 How will the cardiac procedures for AVD be documented? Is there a need for a new data collection process?

Through the CCN Cardiac Registry, CCN has been responsible for tracking all advanced cardiac procedures in Ontario. Dedicated staff at each hospital is accountable for the entry and verification of data in the registry. These staffs include, but are not limited to, Regional Cardiac Care Coordinators (RCCCs), surgical coordinators, and data clerks.

Once a patient is referred for an advanced cardiac procedure, the clinical pathway is documented as the reason for referral. Patient information such as medical history, relevant test results, and existing comorbidities are entered into the CCN Cardiac Registry. These patient characteristics are factored into a calculation of an Urgency Rating Score (URS) as well as a RMWT that are used to help triage patients. The URS and RMWT are under development for TAVI. While the patient is waiting for the procedure or surgery (i.e. wait time), clinical status changes are captured resulting in an adjustment to URS and RMWT, and possible reassignment of the clinical pathway. They are also adjusted based on delays and cancellations. After the patient receives a procedure, all related information is entered into the registry, including: date, type, and details of the procedure.

Data entered into the registry are immediately available for query and analysis. Volumes of the advanced cardiac procedures are verified and submitted by the hospitals to CCN. CCN reports these volumes monthly and annually at the hospital and provincial level.

To standardize documentation and procedural coding, the CCN Cardiac Registry will be used as the source of data for QBP funding volumes and clinical evaluation. The use of the CCN Cardiac Registry does not require a new data collection process. The registry captures comprehensive information on isolated SAVR, SAVR with CABG, and TAVI (i.e., patient characteristics, wait times, and procedural details and volumes). The CCN Cardiac Registry is regularly updated, which allows for changes to and the addition of new data elements (e.g., surgical site infection).

3.6.2 Implications on documentation, physician charting and CAD QBP funding

Prior to QBP implementation, the CCN Cardiac Registry was used as the data source for volumes and funding of advanced cardiac procedures in Ontario. Clinical documentation will not change with the introduction of the AVD QBP.

QBP funding will remain dependent on the accuracy and completeness of data entered into the registry from the patient's chart. At regular intervals, CCN Cardiac Registry reports will be generated to inform funding volumes and for reconciliation.

3.6.3 Clinical engagement

CCN convened the Cardiac QBP Expert Advisory Panel, comprised of clinical, technical and health data experts and other stakeholders, to support the provincial quality agenda related to the HSFR strategy. The

purpose of the panel was to develop, support and promote the utilization and implementation of evidence-based best practice clinical care pathways, quality indicators and pricing models for the AVD QBP.

The provincial CCN Cardiac Registry and CIHI's DAD were used as the primary sources of data to describe practice and outcomes variation across Ontario for advanced cardiac procedures. This work was conducted to support the recommendation for systematic and standardized practices and documentation.

Recommendations of clinical care best practices were derived from available evidence, cardiac society guidelines, experience, and expert consensus. The clinical pathways and quality indicators were validated through a secondary review process via a webcast that engaged a broader audience that included cardiologists, cardiac surgeons, hospital administration, decision support, and other stakeholders.

4.0 Best Practices Guiding the Implementation of AVD QBP

4.1 Best Practice – AVD Clinical Pathway

Best practices⁸ for SAVR, SAVR with CABG, and TAVI for treatment of AVD were defined using a combination of expert consensus and evaluation of available guidelines and literature. The following clinical pathways apply to AVD patients undergoing surgical (SAVR, and SAVR with CABG) and non-surgical treatment (TAVI). The pathways include a small volume of aortic valve repairs including those that had a BAV prior to SAVR. A Heart Team (consisting of an interventional cardiologist, cardiovascular surgeon, cardiologist, cardiac anesthetist, and imaging specialist) approach to management and treatment is recommended in patients with severe AVD.

4.1.1 Evaluation

The ACCF/AHA⁹ and ESC/European Association for Cardio-Thoracic Surgery (EACTS)¹⁰ guidelines for the management of valvular heart disease (VHD) outline the basic components of diagnostic testing and imaging for AVD. Patients with known or suspected valvular disease should be carefully examined using a variety of modalities including physical and history assessment, non-invasive testing such as electrocardiography, and chest x-ray. These initial tests should be followed with comprehensive echocardiographic examination to correlate findings with initial clinical impressions. Ancillary tests such as transesophageal echocardiogram (TEE), multi-slice computed tomography (MSCT), or cardiac magnetic resonance (CMR) imaging, stress testing, and diagnostic cardiac catheterization may be required to determine the extent of disease and optimal treatment.

Transthoracic echocardiography (TTE) is considered the standard imaging modality in the initial evaluation of patients with known or suspected VHD. Echocardiography provides the required information for determination of valve characteristics, etiology, and diagnosis of VHD. Furthermore, follow-up testing by TTE is essential for periodic evaluation of disease progression. Additional testing such as exercise or stress test may be considered for a subset of patients who are asymptomatic with severe VHD. In this subset of patients, exercise testing provides additional prognostic and risk stratification value in assessment of patients with asymptomatic AS.

Cardiac catheterization is indicated for the detection of coronary artery disease in patients with planned aortic valve replacement (surgical or percutaneous).

4.1.2 Patient selection

Patient selection for SAVR is well outlined by ACCF/AHA and ESC VHD guidelines for those with AS. Challenges arise when patients with severe valvular disease and multiple comorbidities present with significant changes in symptoms. This type of patients carries significant surgical risks and suitability for SAVR is determined using surgical risk scores. The most commonly used risk algorithms for cardiac surgery are the Society of Thoracic Surgeons (STS) and EuroSCORE II. Although the STS risk score and

⁸ Best practice refers to a combination of best available evidence and clinical consensus as recommended by the Clinical Expert Advisory Groups

⁹ (Nishimura, et al., 2014)

¹⁰ (Vahanian, et al., 2012)

EuroSCORE II provide information concerning short-term operative risks and benefits, they are not able to predict symptom resolution, quality-of-life improvement, or return to independent living. Current ACCF/AHA guidelines acknowledge that special considerations are required for the management of elderly patients in their 80s and 90s with AS in whom SAVR may be technically feasible, since age-related and comorbid conditions commonly exist in this group.

4.1.3 Education

AVD develops insidiously and patients may not be aware of the symptoms because they gradually limit their daily activity levels. Besides the careful examination of a patient's physical and medical history, patient and family education is an important aspect of healthcare intervention. Education should include disease process, prognosis, treatment options, signs and symptoms of valvular disease, symptoms management, and lifestyle modification. In addition, medications should be reviewed and instructions on proper drug use (e.g., sublingual nitroglycerin) provided to patients and their families, as needed. When reasonable, all patients should receive education prior to procedure or surgery.

To ensure optimal and high-quality care, it is important to make appropriate choices for diagnostic testing, treatments, and procedures. It is recognized that unnecessary tests and treatments may potentially expose patients to harm causing undue stress not only to patients but also financial strain to the healthcare system. Choosing Wisely Canada (CWC), launched in April 2014, was developed to assist physicians and patients to engage in conversation to make informed choices based on definitive evidence. The goal is to change the culture of "more is better" when it comes to treatments and procedures. CWC provides physician recommendations of items physicians and patients should address during consultation.¹¹

4.1.4 Informed consent

As part of the informed consent process, it is recognized that each patient's presentation is unique and the physician must discuss risks and benefits of available approaches or treatment of AVD with the patient or designate and family. This consent process should address three key elements: voluntary consent, mental capacity to consent, and properly informing the patient or designate.¹²

4.1.5 Goals of care

Patients should be given the opportunity to make informed decisions about care and treatment, in partnership with healthcare professionals. For example, the inter-professional team must discuss goals of care with the patient prior to any procedure. With the patient's consent, family and/or caregivers should also be given the opportunity to be involved in decisions about treatment and care. Planned and regular family meetings may be necessary to update the plan of care as the patient condition changes.

¹¹ (Choosing Wisely Canada, 2014)

¹² (Canadian Medical Protective Association (CMPA), 2014)

4.1.6 Pain Management

Pain after cardiac surgery has been considered as one of the most severe types of post-surgical pain and tends to be at its worst in the first 48 hours.^{13 14} Furthermore, the use of the internal mammary artery during CABG has been associated with an increase in post-operative pain.¹⁵ Studies have indicated that high level of acute pain is a predictor of chronic pain after cardiac surgery. The development of chronic pain post cardiac surgery ranges from 21% to 55% and is a key reason for emergency room visits and hospital readmissions.¹⁶

An important issue in the prevention of developing a chronic pain syndrome is the adequate control of pain in the acute phase of surgical recovery. Several key risk factors have been identified in the development of a chronic pain syndrome including the following: presence of preoperative anxiety, depression, high level of stress,¹⁷ age<60, and surgery>2 hours.¹⁸

There are a variety of tools that have been identified as beneficial in the assessment of cardiac surgical patients. The screening tool for addiction risk assessment (STAR) has specifically been designed for patients that will be treated by opioids. Additionally, the Barriers questionnaire focuses on the assessment of patient's beliefs about pain management so these can be addressed before surgery.¹⁹ Preoperative evaluation using these and similar tools will help create a patient centred and customized educational plan to address any misconceptions preoperatively.

Therapies for pain control after cardiac surgery can be managed by a variety of modalities and adequate pain control evaluated by valid and reliable tools such as the Numeric Pain Rating Scale.²⁰ By combining several types of agents and methods to treat pain, research indicates a decrease in narcotic use, a decrease in morbidity, and improved patient satisfaction.²¹

4.1.7 Medical Therapy

Guideline-directed medical therapy is recommended for other medical conditions that pose additional risk to patients with AS.²²

¹³ (Cogan, J, 2010)

¹⁴ (Choinière, et al., 2014)

¹⁵ (Mazzeffi & Khelemsky, 2011)

¹⁶ (Cogan, J, 2010)

¹⁷ (Choinière, et al., 2014)

¹⁸ (Cogan, J, 2010)

¹⁹ (Choinière, et al., 2014)

²⁰ (Cogan, J, 2010)

²¹ (Gritsenko, Khelemsky, Kaye, Validevu, & Urman, 2014)

²² (Nishimura, et al., 2014)

4.1.8 Secondary prevention and prophylaxis

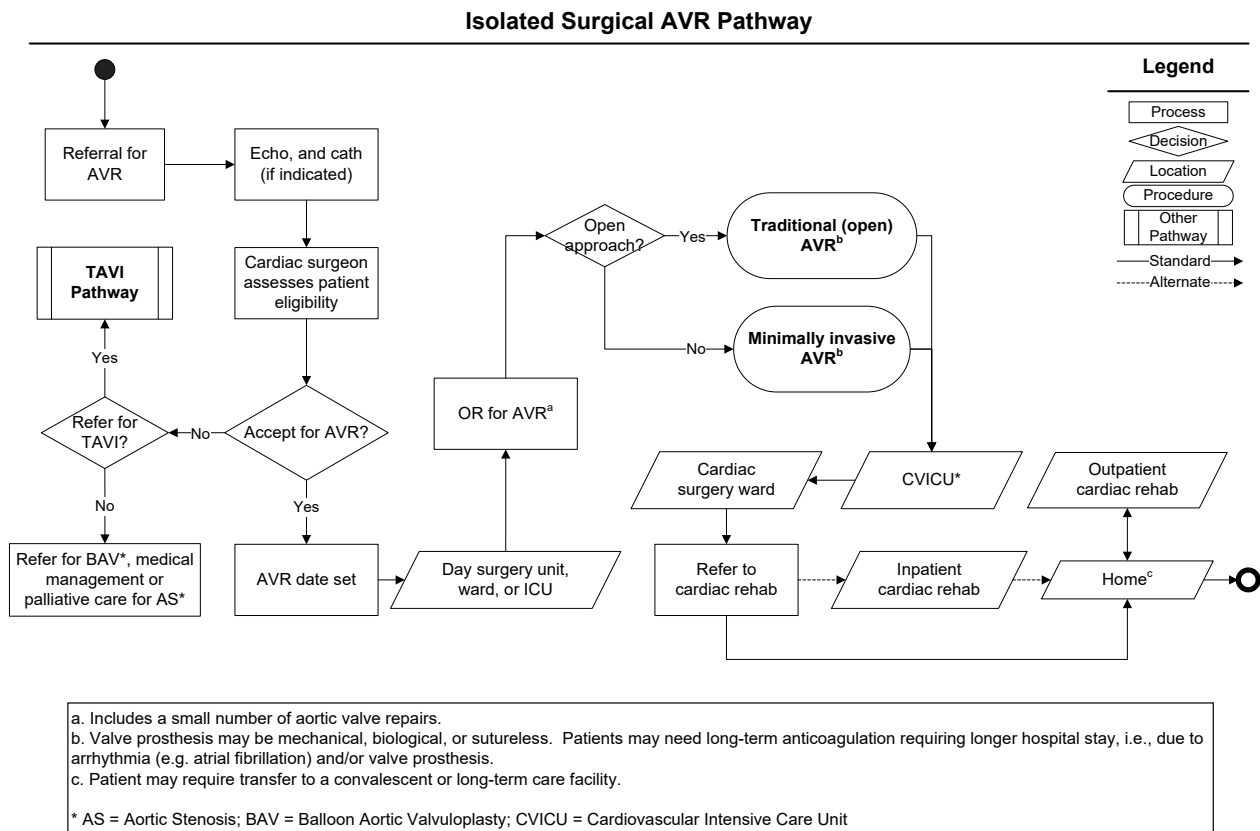
The ACCF/AHA and ESC guidelines explicitly outline secondary prevention for VHD patients with a history of rheumatic fever. It is also deemed reasonable for patients at high risk for developing infective endocarditis to receive prophylaxis prior to dental procedures.

4.2 Current Treatment Options for AVD

4.2.1 Isolated Surgical Aortic Valve Replacement (SAVR)

Information from the STS National Database shows that the operative mortality for isolated SAVR has declined from 3.4% in 2002 to 2.6% today. Many SAVR patients are older, with other comorbid cardiac conditions that increase the risk of stroke, including atrial fibrillation, cardiomyopathy, and carotid stenosis or aortic arch atheroma. However, even carefully selected octogenarians can safely undergo SAVR with extremely low rate of adverse events.²³

Figure 5: Pathway for Isolated SAVR



Not all patients referred for SAVR undergo as extensive diagnostic imaging and testing as TAVI candidates.

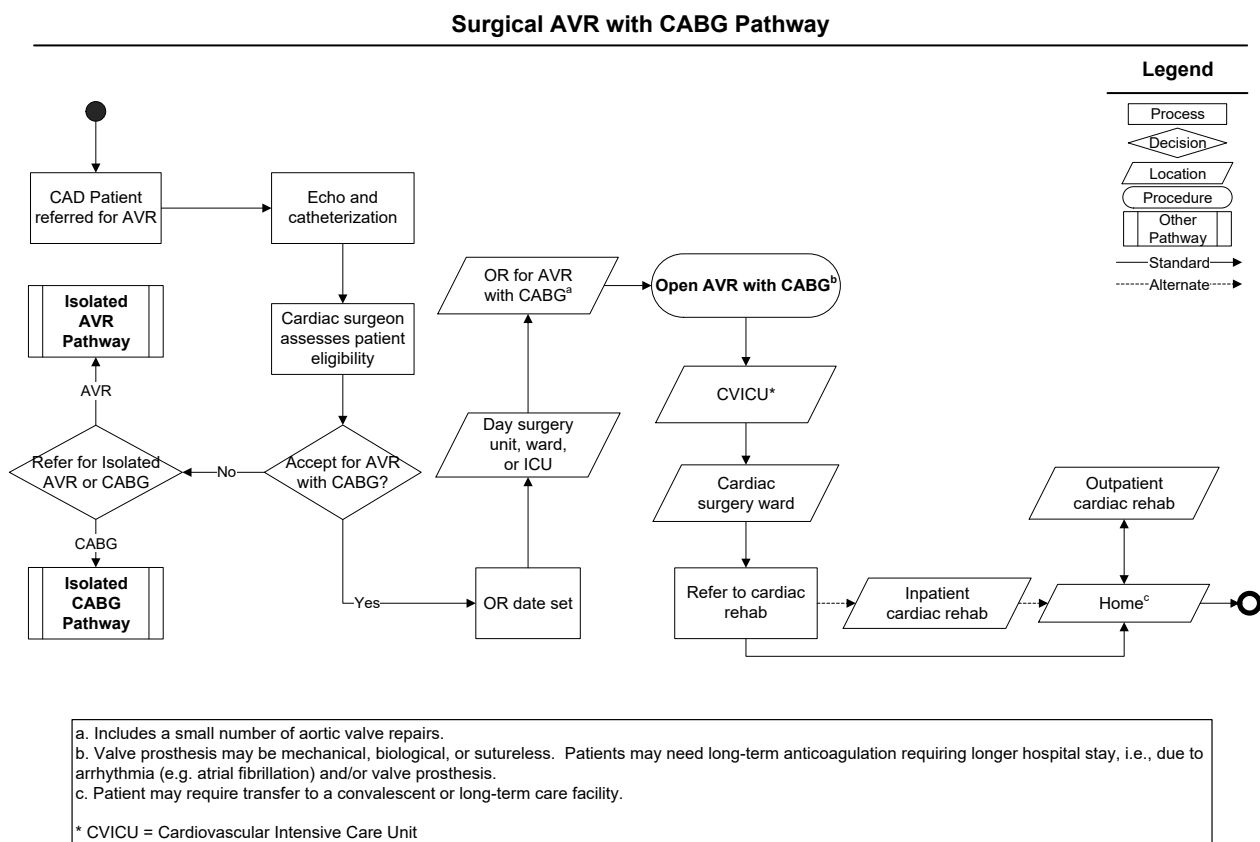
²³ (Harris, et al., 2013)

The evaluation, management and treatment of patients with severe or complex AVD are best achieved by a Heart Team which is composed primarily of a cardiologist, cardiac surgeon, and structural interventionalist (i.e. valve specialist).²⁴ The Heart Team reviews the patient's history, clinical assessment, and test results to determine the most appropriate treatment for the patient. Patients who are candidates for isolated SAVR would undergo basic testing such as electrocardiogram, echocardiogram, and sometimes cardiac catheterization. A patient scheduled for SAVR may be admitted as an outpatient or inpatient prior to surgery (See Figure 5). On the other hand, patients referred for TAVI undergo an additional series of diagnostic imaging and testing, and are then seen by the Heart Team which constitutes a review of existing comorbidities prior to surgery.

4.2.2 Surgical Aortic Valve Replacement (SAVR) with Coronary Artery Bypass Graft (CABG)

Patients with coronary artery disease undergoing SAVR may also have CABG surgery at the same time (See Figure 6). Guidelines recommend that individual clinical judgment is made taking into consideration patient physical and clinical factors when determining the timing of surgical treatment for AVD and CAD.²⁵

Figure 6: Pathway for SAVR with CABG



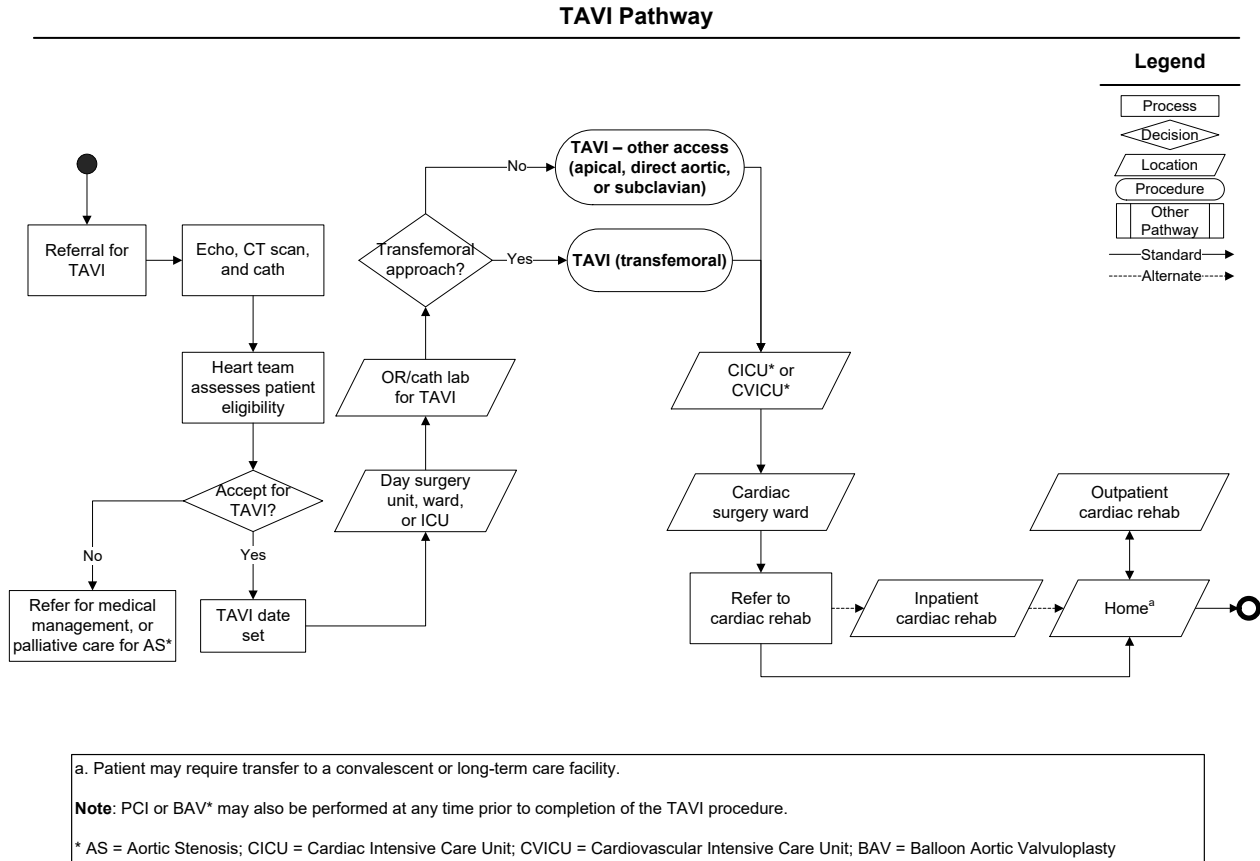
²⁴ (Nishimura, et al., 2014)

²⁵ (Vahanian, et al., 2012)

4.2.3 Transcatheter Aortic Valve Implantation (TAVI)

The decision to treat patients with TAVI is determined by the Heart Team after careful review of patient's history, diagnostic testing and imaging results. Upon acceptance to proceed by both physician and patient, the TAVI procedure is scheduled.

Figure 7: Pathway for TAVI



4.3 Clinical Decision Tree for Patients with Aortic Stenosis²⁶

1. SAVR is the treatment of choice for patients diagnosed with severe symptomatic AS who are considered at intermediate or low surgical risk.
(Strong Recommendation, Moderate-Quality Evidence).
2. TAVI may be offered to selected patients with severe symptomatic AS who would otherwise be considered intermediate to low risk of mortality where there is a consensus of the Heart Team that they are at significantly increased risk of either morbidity or mortality due to special circumstances (e.g., frailty, very advanced age, patent bypass grafts, multivalve disease, etc.).

²⁶ (Webb, et al., 2012)

(Conditional Recommendation, Low-Quality Evidence).

3. Transfemoral TAVI is recommended if:
 - a. The risk of open heart surgery is prohibitive;
 - b. A significant improvement in duration or quality of life is likely; and
 - c. Life expectancy with treatment is likely to exceed to 2 years

(Strong Recommendation, High-Quality Evidence).

4. Patients who are not candidates for open heart surgery or for TAVI using femoral access may be considered for other alternative access procedures (e.g., transapical, transaxillary, or transaortic)

(Conditional Recommendation, Low-Quality Evidence).

Values and preferences. This recommendation places a relatively high weight on the favourable outcomes in recent registry experience with alternative non-transfemoral access techniques and less weight on early feasibility experience.

5. TAVI is a reasonable alternative to SAVR for patients at high-risk ("high-risk" can be defined as a risk of mortality of 8% or major morbidity of 50% within 30 days of surgery as predicted by an experienced cardiac surgeon or by the STS risk calculator) of mortality or major morbidity and:
 - a. Duration and quality of life is likely to be significantly improved by treatment;
 - b. Life expectancy with treatment is likely to exceed 1 to 2 years with treatment; and
 - c. There is a consensus amongst a multidisciplinary Heart Team including cardiologists and surgeons.

(Strong Recommendation, High-Quality Evidence).

Values and preferences. This recommendation places a relatively greater weight on quality of life and morbidity, and less weight on possible unknown differences in valve durability and patient mortality between transcatheter and surgically implanted aortic bioprostheses.

4.4 Pre-procedural or surgical care

Patients undergoing either SAVR or TAVI must have the following completed:

- Informed consent;
- Assess patient's potential need for blood transfusion and undergo appropriate blood management techniques to prevent transfusion;
- Conduct surgical risk assessment using STS and EuroScore II;
- Determine optimal surgical approach based on patient risk factors;
- Preconditioning management of myocardial ischemia is recommended to prevent intraoperative or postoperative MI;
- Clip hair from surgical site if hair interferes with procedure;
- Anesthesia evaluation; and
- Complete pre-operative checklist.

Conduct and document pre-operative tests as needed:

- Document blood investigations results for coagulation studies (i.e. International Normalized Ratio (INR)), complete blood count (including hemoglobin), electrolytes, renal profile including estimated glomerular filtration rate (eGFR), etc.;
- Obtain and provide copy of 12-lead electrocardiogram in patient's record;

- Obtain and document physical assessment and medical history;
- Non-invasive cardiac testing (i.e. stress testing or functional imaging);
- Pre-operative cardiac catheterization, if appropriate; and
- Carotid artery duplex scanning is reasonable in selected patients who are considered to have high-risk features.

Administer pre-medications as needed:

- Prophylactic antibiotics for prevention of post-operative infection;
- Aspirin (100 mg to 325 mg daily);
- Statin therapy; and
- Beta blockers.

Discontinue any medications prior to procedure that may result in increased blood loss or transfusion (i.e. P2Y₁₂ receptor inhibitors, glycoprotein IIb/IIIa inhibitors). The timing of discontinuation should be made according to the recommended schedule.

Blood conservation strategies should be used to limit the need for intraoperative or postoperative blood transfusions that have been shown to increase a patient's morbidity and mortality. The formation of the Ontario Transfusion Coordinators (OnTraC) across Ontario has implemented measures to decrease the needs for blood transfusions for patients undergoing cardiac surgery.²⁷ Such strategies include but are not limited to:

- Management and preoperative correction of anemia;
- Use of cell saver intraoperatively and postoperatively which returns a patients salvaged blood after being washed and filtered;
- Use of drugs that decrease bleeding (i.e., aprotinin, tranexamic acid, and epsilon-aminocaproic acid);
- Blood transfusion is considered reasonable according to the guidelines when hemoglobin is less than 6 g/dL and as indicated by patient's clinical status; Preoperative management of patients on antiplatelet medication i.e. if clopidogrel is used, this should be discontinued at least 5 days before surgery and replaced with low-dose aspirin perioperatively (75-125 mg daily)²⁸; and
- For some patients, the use of preoperative autologous blood transfusion may be an option.²⁹

Patients undergoing cardiac surgery should be treated with an antibiotic as a preventative measure to reduce the risk of infection. Choice of antibiotic will be based on patient presentation, risk of pre-existing infection, and allergies. Those without suspected methicillin-resistant staphylococcus aureus (MRSA) are recommended to receive a first or second generation cephalosporin. Those with known or suspected MRSA should be treated with vancomycin alone or in combination with another antibiotic.³⁰

4.5 Intra-procedural or surgical care

Operating room standards and sterile techniques should be based according to hospital protocol and the recommendations by authoritative organizations such as:

²⁷ (Freedman, Luke, Escobar, Vernich, & Chiavetta, 2008)

²⁸ (Ferrandis, Llau, & Mugarra, 2009)

²⁹ (Canadian Blood Services, 2013)

³⁰ (Hillis, et al., 2011)

- Accreditation Canada International³¹;
- Operating Room Nurses Association of Canada (ORNAC)³²;
- Association of Operating Room Nurses (AORN)³³; and
- Provincial Infectious Diseases Advisory Committee (PIDAC)³⁴.

During surgery, maintenance of normal body temperature is recommended for the majority of procedures, however mild hypothermia may be used at time of aortic cross clamping.

Monitoring should include:

- Physiologic and cardiac monitoring (including heart rate, blood pressure, peripheral oxygen saturation, and body temperature);
- Arterial line for continuous monitoring of hemodynamic status;
- Central venous pressure monitoring;
- Continuous ECG monitoring;
- Temporary transvenous pacemaker as needed;
- Urinary catheter;
- Arterial blood gases, hemoglobin, and electrolytes investigation typically done in conjunction with activated clotting time (ACT) monitoring by anesthesia or perfusion;
- TEE;
- Intra-aortic balloon pump (IABP), when indicated;
- Access to cardio-pulmonary bypass machine;
- Access to point-of-care testing device for ACT monitoring; and
- Access to renal replacement therapy.

4.6 Post-procedural or surgical care

Designated patient care units for post procedural or surgical recovery are imperative for optimal care and better outcome of either SAVR or the group of high-risk patients undergoing TAVI. Although the particulars of post-procedural care will vary from institution to institution, as well as with the maturity of the surgical or TAVI program, the principles of care remain the same that these complex patients should be treated in post-procedural units experienced with both cardiac surgical and interventional cardiology procedures. The following should be considered:

1. Immediate or early extubation, early mobilization, and meticulous attention to the many potential complications in elderly, frail group of patients.
2. Post-anesthetic care unit (PACU) or intensive care unit (ICU). There should be a common care pathway with all patients cared for in the same setting so that the care team is conversant with the care pathway.
3. The monitoring includes vital parameters including fluid balance therapy, renal status, and atrioventricular conduction system. Adequate hydration and avoidance of early diuretic administration is important to minimize renal failure.

³¹ (Accreditation Canada International)

³² (Operating Room Nurses Association of Canada (ORNAC), 2013)

³³ (Association of periOperative Registered Nurses (AORN), 2015)

³⁴ (Provincial Infectious Diseases Advisory Committee (PIDAC), 2012)

4. Completion of perioperative surgical antibiotic prophylaxis, resuming preoperative medications such as beta blockers, and initiation of prophylaxis for venous thromboembolism should be addressed within the first 24 hours after operation.
5. Appropriate pain management regimen should be initiated immediately if necessary after operation in the post procedural unit.
6. When stable, patients should be transferred to a telemetry unit with hemodynamic and electrocardiographic monitoring capability. The duration of monitoring will depend on the patient's response to surgery or procedure and the specific prosthesis used. Patients need to be monitored for risks for brady-arrhythmias requiring pacemaker treatment.

Additional considerations and monitoring may be required at each phase of surgical process (i.e., pre-op, intra-op or post-op) for patients undergoing SAVR with concomitant CABG surgery (Refer to the Isolated CABG section in the CAD QBP Clinical Handbook).

4.7 Transition and follow-up care post SAVR and TAVI

Integration is one of health domains of QBPs. Patient's transition from hospital to home setting, or from inpatient to outpatient, and their integration in community are important aspects of healthcare that should be addressed prior to patient's discharge. An interprofessional approach to discharge planning could potentially improve patient's satisfaction with the hospital discharge process and well-being after discharge.³⁵ Patient-centred interprofessional discharge and follow-up consultation and planning with patient and/or family may occur as soon as the patient is admitted. Discharge plan should include, but not be limited to:

- Post procedure/surgery education;
- Medical management;
- Access to in-patient or out-patient rehabilitation;
- Information regarding return to work;
- Lifestyle modification education; and
- Discussion about follow-up clinic visits.

Patient access to community supports requires transfer of accountability and referrals to primary care providers and community programs with defined documentation and communication. A systematic referral is vital for cardiac rehabilitation in improving patient's participation in supervised exercise programs.³⁶ In order for patients to achieve optimal benefit from exercise programs, cardiac rehabilitation should commence within 30 days of hospital discharge.³⁷ Cardiac rehabilitation is recommended for patients after surgical treatment of VHD.³⁸ Similarly, smoking cessation in-hospital education and cessation therapy should be offered to all identified smokers among AVD patients particularly those with concomitant CAD.³⁹

³⁵ (Preen, et al., 2005)

³⁶ (Grace, et al., 2011)

³⁷ (Dafoe, Arthur, Stokes, Morrin, & Beaton, 2006)

³⁸ (Butchart, et al., 2005)

³⁹ (Hillis, et al., 2011)

5.0 Implementation of Best Practices

While there exists a high level of care provided to AVD patients, variability exists in practice, outcomes and indicators of efficiency across Ontario suggesting opportunities for improvements in the delivery of cardiac services. Implementation of best practices based on established guidelines may improve system efficiencies and reduce the regional disparities in clinical outcomes, benefiting patients and the health-care system. As a system support for cardiac care services, CCN acts to enhance quality of care and outcomes, and monitor timely access for advanced cardiac procedures. In addition to CCN, the network should include stakeholders involved in the delivery of services, including interprofessional care providers in hospitals, outpatient centres, and administrators with a standard approach to support evidence-based and effective diagnostic and therapeutic management for AVD patients.

An organization-specific implementation plan may include:

- A gap assessment of the current standard of practice and the recommended best practice recognizing the need(s) for change;
- An assessment of the readiness of the institution to provide a full breadth of care and possible barriers to implementation;
- Identification of stakeholders and their required involvement;
- Dedicated individual(s) to provide support for education and implementation;
- Timelines for implementation;
- Forums for discussion and education;
- Roll out plans focused around the unique areas identified for changes;
- Follow-up evaluation of progress;
- Participation in a formal provincial cardiac network and registry; and
- A sustainability plan for maintaining the Best Practice Standards.

Details of each of these steps are clearly outlined in 'Toolkit to Support the Implementation of Quality-Based Procedures' published by the Ontario Hospital Association (OHA) available at

https://www.oha.com/KnowledgeCentre/Library/Toolkits/Documents/OHA_QBProcedures_toolkit_FNL.pdf.

According to OHA, there are three key success factors to QBP implementation: senior leadership support, clinician engagement, and high quality data. Furthermore, organizations should consider engaging patients in this process. Patient participation in the evaluation and implementation of AVD QBP is one of the ways in which patient's values and perspectives are heard and integrated into health decisions.

Data management requires consistent and complete data entry for every data field in CCN Cardiac Registry by dedicated personnel (i.e. RCCCs or Data Clerks). Training and ongoing support for new and existing personnel responsible for data entry are provided by CCN. Education of hospital decision support personnel on CCN Cardiac Registry may also be provided by CCN. The CCN database is accessible to authorized users with the ability to generate custom reports that can be used for hospital administrative, research, or clinical data.

The addition of new and future cardiac procedures in AVD QBP would require the education and training not only of personnel involved in these procedures, but also of RCCCs, Data Clerks, hospital clinical decision support, and relevant hospital stakeholders. CCN will continue its process of updating the cardiac registry on a regular basis to reflect accurate collection of recommended procedural details, quality indicators, and outcome measures.

6.0 What Does It Mean for Interprofessional Teams?

Patient-centeredness in health care is one of the quality domains of QBPs. Best practice dictates that it is critical to integrate interprofessional collaborative health care delivery models into the care of AVD patients to achieve and maintain quality and patient-centeredness. The WHO defines interprofessional *collaborative practice* in health care as occurring “when multiple health workers from different professional backgrounds work together with patients, families, caregivers and communities to deliver the highest quality of care.”⁴⁰

Standardization of best practices for treatment of AVD will require individual hospitals to consider a coordinated interprofessional team approach to AVD involving a network of care providers with various expertise including but not limited to, cardiovascular surgeon, structural interventionalist, cardiologist, anaesthesiologist, anaesthesia assistant, nurses, nurse practitioners, intensive care practitioners, technologists, pharmacists and allied health providers to facilitate continuity of both inpatient and outpatient care. In addition, the contribution of decision support and health records departments should be considered for accurate coding and documentation of advanced cardiac procedures. Innovative solutions are required to plan for and meet the future needs of AVD care and maintain levels of service delivery. As a provincial system support, CCN is well-positioned to lead novel and innovative initiatives to address gaps and meet current and future needs in delivery of cardiovascular care services.

How does the AVD best practice pathway align with clinical practice?

The recommendations for best practice of AVD are based on evidence from current literature, guidelines and consensus of the clinical expert group. The pathways have been derived from current national guidelines such as those described within the ACCF/AHA and ESC Guidelines for the Management of Patients with Valvular Heart Disease and the Canadian Cardiovascular Society Position Document on TAVI. Also, taking into account current AVD protocols and processes in place in Ontario hospitals and the collective experience of the clinical expert panel which shaped the development of the pathways recommended herein. Alignment of these recommendations with current clinical practice will vary across institutions; however, it is felt that many hospitals are currently following similar practices.

Will adoption of the AVD pathway change current clinical practice?

It is expected that this will provide standardization in clinical practice, however the extent of change will vary based on the individual circumstances of each hospital's adoption of the recommended pathway. Adoption of evidence-based best practices is expected to improve patient outcomes through:

- Systematic referrals and viable links to community and outpatient programs;
- Interprofessional and patient-centred approach to care;
- Programmatic and team approach to management and treatment of complex AVD;
- Standardized patient education and discharge planning;
- Application of risk reduction strategies; and
- Effective medication management.

⁴⁰ (Health Professions Networks Nursing & Midwifery Human Resources for Health, 2010)

7.0 Service Capacity Planning

The impact that QBP-based funding will have on hospital volumes of cardiac revascularization procedures is unknown. Careful volume monitoring and planning will be required to ensure that QBP-based funding implementation does not disrupt current service capacity. Currently the volume of AV surgery performed annually in Ontario has remained relatively constant for the past few years. It is not expected that this trend should be affected by implementation of QBP- based funding. It is doubtful that any new cardiac surgery centres will be required in Ontario to support changes in the volumes of SAVR.

Table 3. Volumes of AVD Procedures Performed in Ontario

Procedure	2009/10	2010/11	2011/12	2012/13	2013/14
Isolated SAVR	982	979	1015	985	1019
SAVR and CABG	820	845	874	842	784
TAVI	114	169	219	335	477

Data Source: CCN Cardiac Registry

The volume of TAVI procedures in Ontario has been steadily increasing over the past five fiscal years (see Table 3). It is expected that TAVI volumes will continue to increase based on clinical indication and evidence. Currently, TAVI is reserved for patients at high-risk for conventional SAVR.

8.0 Performance Evaluation and Feedback

An integrated scorecard for AVD will be developed to allow the Ministry to measure changes in clinical practice resulting from implementation of QBP-based funding for treatment of AVD. This section of the handbook provides some high level recommendations for indicators from which to build this scorecard, based on existing work done to measure the quality of care of procedures designed to treat AVD in Ontario.

CCN is responsible for maintaining the CCN Cardiac Registry in Ontario. This registry is a comprehensive, provincial database which can be used to track the volume and wait times of procedures performed to treat AVD, including conventional SAVR as well as TAVI, in Ontario along with many important clinical variables associated with these procedures. When linked to provincial health abstract databases these data can be used to calculate post-procedural outcomes and track standardized performance across the province. CCN has recently started reporting on long-term and post-procedural outcomes following SAVR in Ontario in 2012 and on select outcomes following TAVI. CCN is committed to continue to review and develop indicators to evaluate the performance of AVD treatment in Ontario.

Currently, the quality of care provided to patients with AVD in Ontario is high, with outcomes comparable to other Canadian and international jurisdictions. For TAVI, outcomes in Ontario are comparable to those released from TAVI clinical trials (the PARTNER trial). This has been demonstrated for SAVR in recent outcomes reports released by CCN and for TAVI in confidential reports released to the Ministry and to the individual TAVI programs. Based on these reports, there are a number of indicators that have been reported by CCN in the past and are ready to be implemented as part of the integrated score card immediately.

8.1 Quality Indicators for Immediate Implementation:

A. General Quality Indicators

1. Risk-adjusted 30-day and 1-year post procedure mortality rates
2. Post-surgical stroke within 30 days and one year
3. Mortality on wait list (for **TAVI**)
4. Rate of 30-day all-cause readmission
5. Risk-adjusted blood product (red blood cells, whole blood, plasma, and platelets) transfusion rates within episode of care
6. Rate of readmission to ICU within 48 hours from inpatient locations
7. Total length of stay (TLOS)
8. Mean and 90th percentile wait times in days
9. Percentage of patients referred to cardiac rehabilitation program upon discharge

B. AVD QBP-Specific Quality Indicators

1. Rate of long ICU length of stay (LOS) (≥ 4 days) (for **isolated SAVR** and **SAVR with CABG**)
2. Rate of long inpatient wait (≥ 5 days) (for **TAVI**)
3. Rate of non-transfemoral access (for **TAVI**)

8.2 Proposed Quality Indicators for Future Development

There are also a number of indicators that have not previously been reported and would require further development before being implemented as part of the integrated score card.

1. Percentage of cardiac procedures completed within the recommended wait time
2. Rate of vascular access site complications (for TAVI)
3. Rate of renal failure within episode of care
4. Rate of moderate to severe paravalvular aortic insufficiency (AI) at 30 days (or first follow-up) post TAVI
5. Rate of surgical site infection

8.3 Integrated Scorecard

In introducing the QBPs the ministry has a strong interest in:

1. Supporting monitoring and evaluation of the impact (intended and unintended) of the introduction of QBPs
2. Providing benchmark information for clinicians and administrators that will enable mutual learning and promote on-going quality improvement
3. Providing performance-based information back to Expert Panels to evaluate the impact of their work and update as required in real time

There was recognition that reporting on a few system-level indicators alone would not be sufficient to meet the Ministry's aim of informing and enabling quality improvement initiatives at the provider-level. Therefore measures meaningful to hospitals and clinicians that are interpretable and have demonstrable value in improving the quality of care provided to patients are also of utmost importance.

To guide the selection and development of relevant indicators for each QBP, the Ministry, in consultation with experts in evaluation and performance measurement, developed an approach based on the policy objectives of the QBPs and a set of guiding principles. This resulted in the creation of an integrated scorecard with the following six quality domains:

- Effectiveness (including safety)
- Appropriateness
- Integration
- Efficiency
- Access
- Patient-centeredness

The scorecard is based on the following guiding principles:

- **Relevance** – the scorecard should accurately measure the response of the system to introducing QBPs
- **Importance** – to facilitate improvement, the indicators should be meaningful for all potential stakeholders (patients, clinicians, administrators, LHINs and the Ministry)
- **Alignment** – the scorecard should align with other indicator-related initiatives where appropriate
- **Evidence** – the indicators in the integrated scorecard need to be scientifically sound or at least measure what is intended and accepted by the respective community (clinicians, administrators and/or policy-decision makers)

A set of evaluation questions was identified for each of the QBP policy objectives outlining what the Ministry would need to know in order to understand the intended and unintended impact of the introduction of QBPs. These questions were translated into key provincial indicators resulting in a QBP scorecard (see table below).

Table 4: Quality Domains

Quality Domain	What is being measured?	Key provincial indicators
Effectiveness	What are the results of care received by patients and do the results vary across providers that cannot be explained by population characteristics as well as is care provided without harm?	<ol style="list-style-type: none"> 1. Proportion of QBPs that improved outcomes 2. Proportion of QBPs that reduced variation in outcome 3. Proportion of (relevant) QBPs that reduced rates of adverse events and infections
Appropriateness	Is patient care being provided according to scientific knowledge and in a way that avoids overuse, underuse or misuse?	<ol style="list-style-type: none"> 4. Proportion of QBPs that reduced variation in utilization 5. Proportion of (relevant) QBPs that saw a substitution from inpatient to outpatient/day surgery 6. Proportion of (relevant) QBPs that saw a substitution to less invasive procedures 7. Increased rate of patients being involved in treatment decision 8. Proportion of (relevant) QBPs that saw an increase in discharge dispositions into the community
Integration	Are all parts of the health system organized, connected and work with another to provide high quality care?	<ol style="list-style-type: none"> 9. Reduction in 30-day readmissions rate (if relevant) 10. Improved access to appropriate primary and community care including for example psychosocial support (e.g. personal, family, financial, employment and/or social needs) 11. Coordination of care (TBD) 12. Involvement of family (TBD)
Efficiency	Does the system make best use of available resources to yield maximum benefit ensuring that the system is sustainable for the long term?	<ol style="list-style-type: none"> 13. Actual costs vs. QBP price
Access	Are those in need of care able to access services when needed?	<ol style="list-style-type: none"> 14. Increase in wait times for QBPs / for specific populations for QBP 15. Increase in wait times for other procedures 16. Increase in distance patients have to travel to receive the appropriate care related to the QBP 17. Proportion of providers with a significant change in resource intensity weights (RIW)
Patient-Centeredness (to be further developed)	Is the patient/user at the center of the care delivery and is there respect for and involvement of patients' values, preferences and expressed needs in the care they receive? (TBC)	<ol style="list-style-type: none"> 18. Increased rate of patients being involved in treatment decision 19. Coordination of care (TBD) 20. Involvement of family (TBD)

It should be noted that although not explicitly mentioned as a separate domain, the equity component of quality of care is reflected across the six domains of the scorecard and will be assessed by stratifying indicator results by key demographic variables and assessing comparability of findings across sub-groups. Where appropriate, the indicators will be risk-adjusted for important markers of patient complexity so that they will provide an accurate representation of the quality of care being provided to patients.

The Ministry and experts recognized that to be meaningful for clinicians and administrators, it is important to tie indicators to clinical guidelines and care standards. Hence, advisory groups that developed the best practices were asked to translate the provincial-level indicators into QBP-specific indicators. In consulting the advisory groups for this purpose, the Ministry was interested in identifying indicators both for which provincial data is readily available to calculate and those for which new information would be required. Measures in the latter category are intended to guide future discussion with Ministry partners regarding how identified data gaps might be addressed.

In developing the integrated scorecard approach, the Ministry recognized the different users of the indicators and envisioned each distinct set of measures as an inter-related cascade of information. That is, the sets of indicators each contain a number of system or provincial level measures that are impacted by other indicators or driving factors that are most relevant at the Local Health Integration Networks (LHINs), hospital or individual clinician level. The indicators will enable the province and its partners to monitor and evaluate the quality of care and allow for benchmarking across organizations and clinicians. This will in turn support quality improvement and enable target setting for each QBP to ensure that the focus is on providing high quality care, as opposed to solely reducing costs.

It is important to note that process-related indicators selected by the expert panels will be most relevant at the provider level. The full list of these measures is intended to function as a 'menu' of information that can assist administrators and clinicians in identifying areas for quality improvement. For example, individual providers can review patient-level results in conjunction with supplementary demographic, financial and other statistical information to help target care processes that might be re-engineered to help ensure that high-quality care is provided to patients.

Baseline reports and regular updates on QBP specific indicators will be included as appendices to each QBP Clinical Handbook. Reports will be supplemented with technical information outlining how results were calculated along with LHIN and provincial-level results that contextualize relative performance. Baseline reports will also be accompanied by facility-level information that will facilitate sharing of best practices and target setting at the provider-level.

The Ministry recognizes that the evaluation process will be on-going and will require extensive collaboration with researchers, clinicians, administrators and other relevant stakeholders to develop, measure, report, evaluate and, if required, revise and/or include additional indicators to ensure that the information needs of its users are met.

9.0 Support for Change

CCN, in collaboration with the QBP expert panel for AVD, will continue to provide support and ongoing education to the provincial cardiac centres related to these QBPs. In addition, CCN will employ its working groups that deal specific to AVD (Cardiovascular Surgery, Transcatheter Therapeutics and New Technology (T3), Heart Failure, Cardiovascular Chronic Disease Management, and Echocardiography) to support the implementation of AVD QBP.

The Ministry, in collaboration with its partners, will deploy a number of field supports to support adoption of the funding policy. These supports include:

Committed clinical engagement with representation from cross-sectoral health sector leadership and clinicians to champion change through the development of standards of care and the development of evidence-informed patient clinical pathways for the QBPs.

Dedicated multidisciplinary clinical expert group that seek clearly defined purposes, structures, processes and tools which are fundamental for helping to navigate the course of change.

Strengthened relationships with Ministry partners and supporting agencies to seek input on the development and implementation of QBP policy, disseminate quality improvement tools, and support service capacity planning.

Alignment with quality levers such as the Quality Improvement Plans (QIPs). QIPs strengthen the linkage between quality and funding and facilitate communication between the hospital board, administration, providers and public on the hospitals' plans for quality improvement and enhancement of patient-centered care.

Deployment of a Provincial Scale Applied Learning Strategy known as IDEAS (Improving the Delivery of Excellence Across Sectors). IDEAS is Ontario's investment in field-driven capacity building for improvement. Its mission is to help build a high-performing health system by training a cadre of health system change agents that can support an approach to improvement of quality and value in Ontario.

We hope that these supports, including this Clinical Handbook, will help facilitate a sustainable dialogue between hospital administration, clinicians, and staff on the underlying evidence guiding QBP implementation. The field supports are intended to complement the quality improvement processes currently underway in your organization.

10.0 Frequently Asked Questions

1. Will physician payment models change as a result of QBP implementation?

At this time, physician payment models and OHIP fee schedules, as they relate to QBPs, will remain unchanged. Physicians currently working under fee-for-service will continue to submit claims to OHIP for consultations, performing the procedure and follow-up.

2. How will hospitals be compensated for providing care to more complex patients under the QBP process?

Patient complexity, co-morbid conditions, and procedural factors were taken into account in the costing/pricing methodology used for Cardiac QBP.

3. Is valvuloplasty included in the AVD QBP?

Generally, valvuloplasty procedures are performed as a bridge for TAVI or aortic valve surgery. Since the overall volume of these procedures is small, valvuloplasty cases are accounted for in the AVD QBP.

11.0 Membership

NAME	TITLE	ORGANIZATION
Clinical		
Cohen, Dr. Eric	Interventional Cardiologist Deputy Chief, Division of Cardiology Schulich Heart Centre Associate Professor, Department of Medicine, University of Toronto	Sunnybrook Health Sciences Centre
Feindel, Dr. Chris	Cardiac Surgeon Antonio & Helga DeGasperis Chair in Clinical Outcomes Research in Cardiac Surgery Professor of Surgery, University of Toronto	University Health Network
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Chen, Ms. Jane	Manager, Case Costing and Activity Reporting	University Health Network
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Branco, Marta	Health Information Specialist	St. Michael's Hospital
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Administrative		
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Nieminen, Mr. Tomi	Director, Decision Support Services	St. Michael's Hospital
Petersen, Mr. Ben	Vice President, Corporate Services and Chief Financial Officer	Royal Victoria Regional Health Centre
Sherrard, Ms. Heather	Vice President, Clinical Services	University of Ottawa Heart Institute
Young, Mr. Michael	Executive Vice President, Corporate	Sunnybrook Health Sciences Centre
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Appendix A – List of Abbreviations

ACCF	American College of Cardiology Foundation	LHIN	Local Health Integration Network
AHA	American Heart Association	LOS	Length of Stay
AS	Aortic Stenosis	Ministry	Ministry of Health and Long-Term Care
AVD	Aortic Valve Disease	NACRS	National Ambulatory Care Reporting System
BAV	Balloon Aortic Valvuloplasty	PARTNER	Placement of Aortic Transcatheter Valve
CABG	Coronary Artery Bypass Graft	QBP	Quality-Based Procedure
CCS	Canadian Cardiovascular Society	RCCC	Regional Cardiac Care Coordinator
CCN	Cardiac Care Network of Ontario	RMWT	Recommended Maximum Wait Time
CIHI	Canadian Institute for Health Information	SAVR	Surgical Aortic Valve Replacement
DAD	Discharge Abstract Database	STS	Society of Thoracic Surgeons
ESC	European Society of Cardiology	TAVI	Transcatheter Aortic Valve Implantation
HBAM	Health Based Allocation Model	TEE	Transesophageal Echocardiogram
HSFR	Health System Funding Reform	VHD	Valvular Heart Disease
ICU	Intensive Care Unit		

Appendix B – CCN Cardiac Registry Code Definition

When there are two or more procedures within a single admission, the case will only fall under only one procedure group, according to the following hierarchy. If an AVD patient also has a CAD procedure within the same admission, the encounter will be grouped within the AVD QBP only.



General Inclusion Criteria

(«Removal Date» - «Date of Birth») ≥ 20
AND («Authority Issuing» (Wait Times Data)='CANON' **OR** («Authority Issuing» (Wait Times Data)=NULL **AND** «Authority Issuing» (Patient Profile)='CANON'))
AND «Funding Source»='H'
AND «Removal Reason»='PS'
AND «Discharge/Transfer Date» is not NULL
AND «Booking Status»="Active"

Inpatient/Outpatient Inclusions by Cost Group

TAVI	Inpatient Only
SAVR with CABG	
Isolated SAVR	

Inclusions by QBP Group

QBP Group	TAVI	«Trans Catheter Aortic Valve Intervention (TAVI)»='Y'
	SAVR with CABG	«Aortic Valve Surgery»='Y' AND «Bypass Surgery»='Y' AND «Mitral Valve Surgery»='N' AND «Other Valve Surgery»='N' AND «Tricuspid Valve Surgery»='N' AND «Aortic Surgery»='N' AND «Trans Catheter Aortic Valve Intervention (TAVI)»='N'
	Isolated SAVR	«Aortic Valve Surgery»='Y' AND «Bypass Surgery»='N' AND «Mitral Valve Surgery»='N' AND «Other Valve Surgery»='N' AND «Tricuspid Valve Surgery»='N' AND «Aortic Surgery»='N' AND «Trans Catheter Aortic Valve Intervention (TAVI)»='N'

