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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Ontario

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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) QBP.

The Cardiac Care Network of Ontario (CCN) serves as a system support to the Ministry of Health and Long-Term Care, Local Health Integration Networks, 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

Historically, a large portion of health service providers' funding has been grounded on:

- A base annualized funding (global allocation), which is used to maintain day-to-day operations including staff wages and benefits, overhead costs and service/maintenance contracts;
- New incremental funding, based on a funding formula, which takes into account demographics and acuity; and
- Growth funding targeted at fastest growing communities, hospital type (i.e. small/rural to cover service gaps, academic hospital sites to cover higher cost and acuity).

There needs to be a move to better integrate and align funding mechanisms across sectors to respond to volume and mix of services that meet population needs through the pathways of care for patients. By focusing on an enhanced alignment between high quality patient care and funding, reductions in variation in practice across the province can be achieved. The results of such reduction in practice variation facilitate the adoption of best clinical evidence-informed practices, ensuring our patients receive the right care at the right place and at the right time.

In response to these fiscal challenges, as of April 1, 2012, the Ministry of Health and Long-Term Care (Ministry) has implemented Health System Funding Reform (HSFR). Over the fiscal years 2012/13 to 2014/15, HSFR will shift much of Ontario's health care system funding for hospitals and Community Care Access Centres (CCACs) away from the current global funding allocation towards paying for activity and patient outcomes, to further support quality, efficiency and effectiveness in the health care system.

HSFR is predicated on the tenets of ***Ontario's Action Plan for Health Care*** and is aligned 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.

HSFR is comprised of three key components:

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

2.1 What are we moving towards?

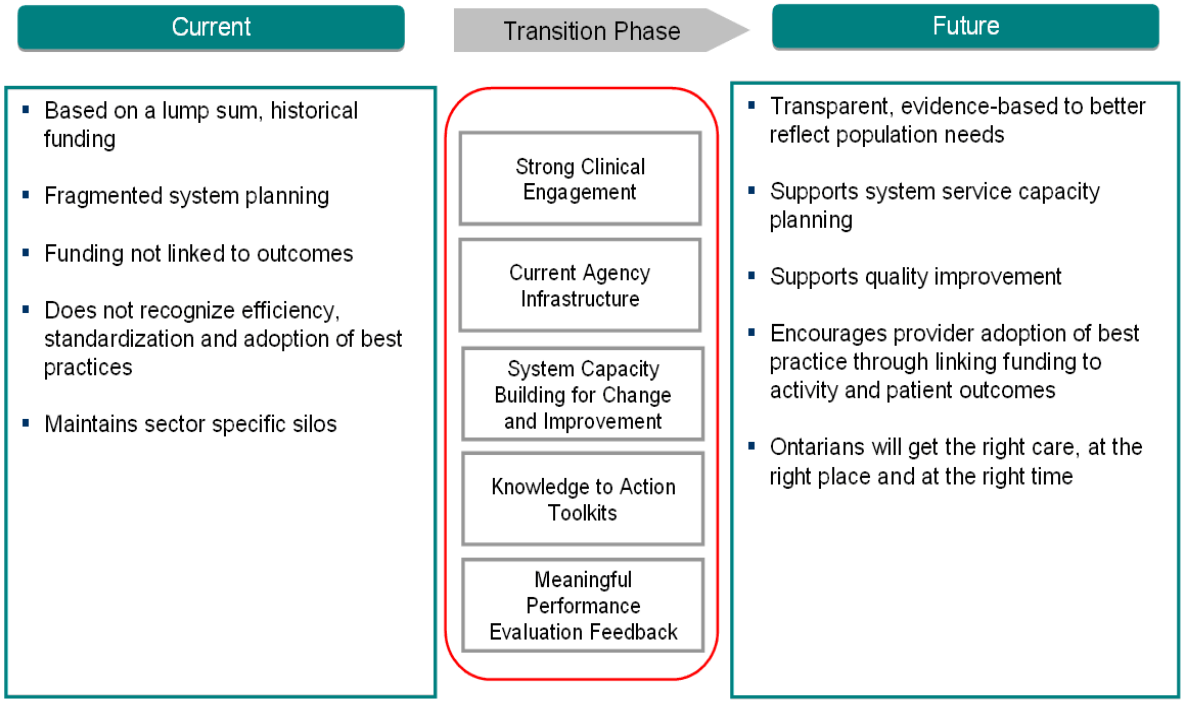
Prior to the introduction of HSFR, a significant proportion of hospital funding was allocated through a global funding approach, with specific funding for select provincial programs, wait times services, and other targeted activities. A global funding approach may not account for complexity of patients, service levels, and costs, and may reduce incentives to adopt best practices that result in improved patient outcomes in a cost-effective manner.

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 provide incentives to health care providers to become more efficient and effective in their patient management by accepting and adopting best practices that ensure Ontarians receive the right care at the right time and in the right place.

The variations in patient care evident in the global funding approach warrant the move towards a system where 'money follows the patient' (Figure 1).

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

Figure 1: The Ontario government is committed to moving towards patient-centred, evidence-informed funding that reflects local population needs and incents delivery of high quality care.



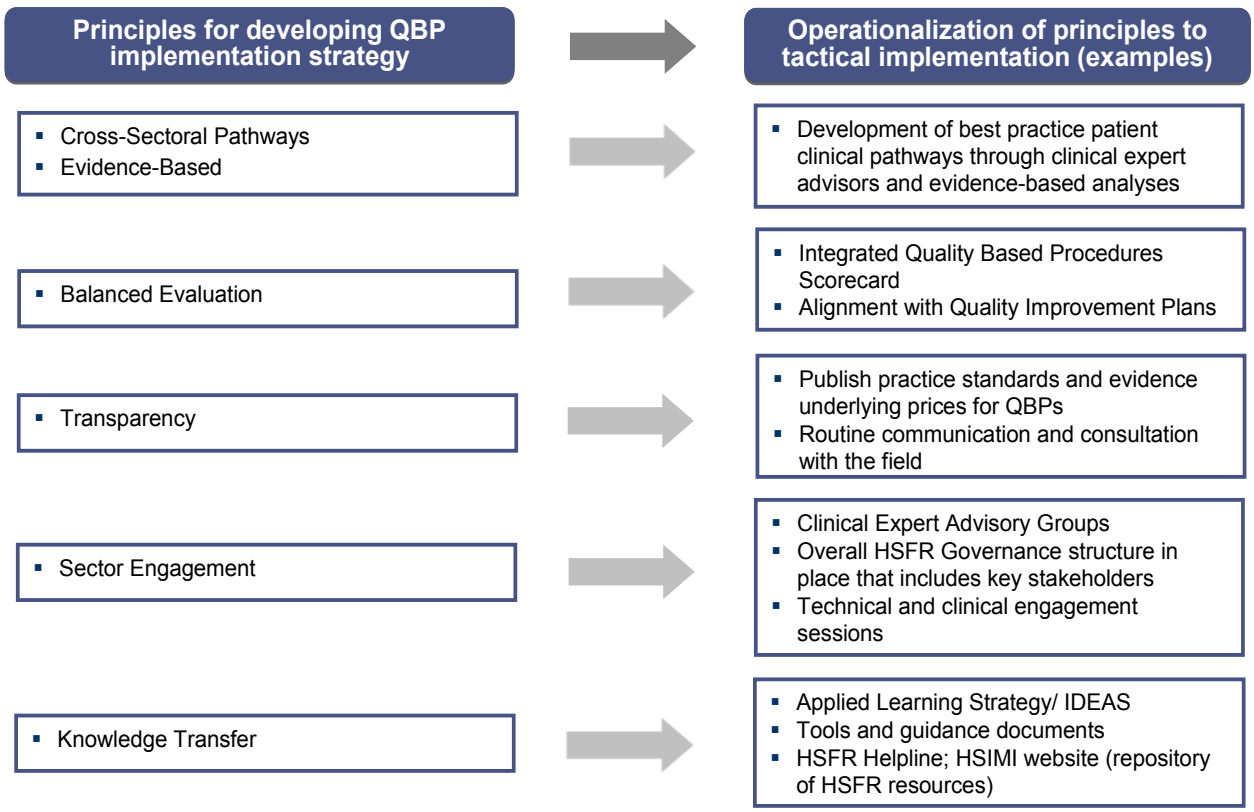
2.2 How will we get there?

The Ministry has adopted a multi-year implementation strategy to phase in the HSFR strategy and will make modest funding shifts beginning April 2012. A three-year outlook has been provided to the field to support planning for upcoming funding policy changes.

The Ministry has released a set of tools and guiding documents to further support the field in adopting the funding model changes. For example, a Quality-Based Procedure (QBP) interim list has been published for stakeholder consultation and to promote transparency and sector readiness. The list is intended to encourage providers across the continuum to analyze their service provision and infrastructure in order to improve clinical processes and where necessary, build local capacity. However, as implementation evolves, the interim list will continue to undergo further refinements pending stakeholder feedback and advice from the QBP Clinical Expert Advisory Groups.

The successful transition from the current 'provider-centred' funding model towards a 'patient-centred model' will be catalyzed by a number of key enablers and field supports. These enablers translate to actual principles that guide the development of the funding reform implementation strategy related to QBPs. These principles further translate into operational goals and tactical implementation, as presented in Figure 2.

Figure 2: Principles guiding the implementation of funding reform related to Quality-Based Procedures.



2.3 What are Quality-Based Procedures?

QBPs involve clusters of patients with clinically related diagnoses or treatments. Aortic valve disease (AVD) was chosen as a QBP using an evidence and quality-based selection framework that identifies opportunities for process improvements, clinical re-design, improved patient outcomes, and enhanced patient experience and potential cost savings.

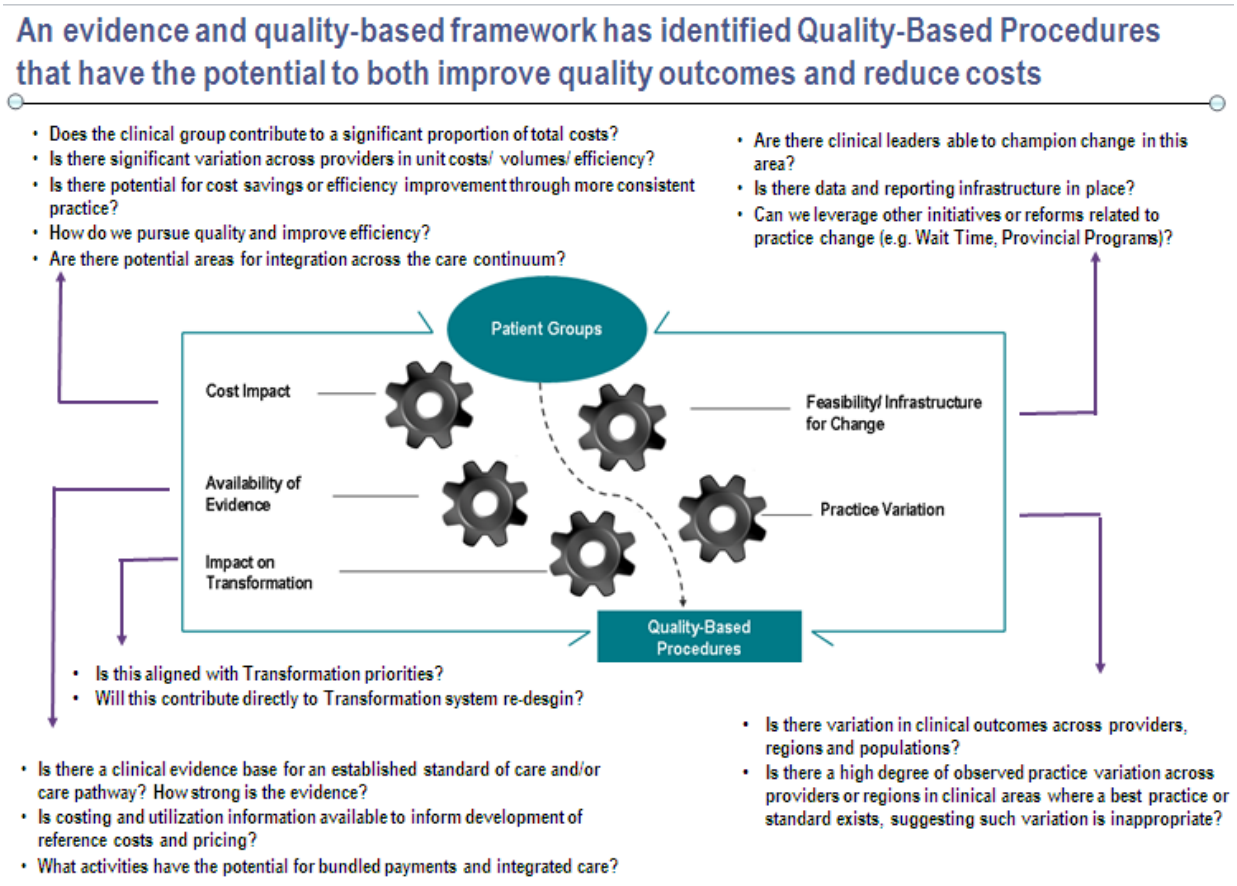
The evidence-based framework used data from:

- Cardiac Care Network (CCN) Cardiac Registry; and
- The Canadian Institute for Health Information (CIHI) 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 was used from the Ontario Case Costing Initiative (OCCI) and Ontario Cost Distribution Methodology (OCDM). Evidence from Canada and other jurisdictions and World Health Organization (WHO) reports was used to assist with the patient clusters and the assessment of potential opportunities.

The evidence-based framework assessed patients using five perspectives, as presented in Figure 3. This evidence-based framework has identified QBPs that have the potential to improve quality of care, standardize care delivery across the province, and show increased cost efficiency.

Figure 3: Evidence-Based Framework



Practice Variation

The CCN Cardiac Registry is the provincial repository of all advanced cardiac procedures in Ontario. Patient demographics, comorbidities, and procedural details are collected from all advanced cardiac centres for the registry. The DAD has every Canadian patient discharge (except Quebec) coded and abstracted for over 50 years. This information is used to identify patient transition through the acute care sector including discharge locations, expected lengths of stay, and readmissions for every patient based on their diagnosis and treatment, age, gender, co-morbidities and complexities, and other condition-specific data. A demonstrated large practice or outcome variance may represent a significant opportunity to improve patient outcomes by reducing this practice variation and focusing on evidence-informed practice. 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. Ontario has detailed case costing data from some hospitals as far back as 1991 for all patients discharged from some case costing hospitals, as well as daily utilization and cost data by department, by day and by admission.

Availability of Evidence

A significant amount of research has been completed both in Canada and across the world to develop and guide clinical practice. Working with clinical experts, best practice guidelines and clinical pathways can be developed for these QBPs and appropriate evidence-informed indicators can be established to measure the quality of QBP care and help identify areas for improvement at the provider level and to monitor and evaluate the impact of QBP implementation.

Feasibility/Infrastructure for Change

Clinical leaders play an integral role in this process. Their knowledge of the patients and the care provided or required represents an invaluable component of assessing where improvements can and should be made. Many groups of clinicians have already formed and provided evidence and the rationale for care pathways and evidence-informed practice.

Cost Impact

The selected QBP should have as a guide no less than 1,000 cases per year in Ontario and represent at least one per cent of the provincial direct cost budget. While cases that fall below these thresholds may in fact represent improvement opportunity, the resource requirements to implement a QBP may inhibit the effectiveness for such a small patient cluster, even if there are some cost efficiencies to be found. Clinicians may still work on implementing best practices for these patient sub-groups, especially if it aligns with the change in similar groups. However, at this time, there will be no funding implications. The introduction of evidence into agreed-upon practice for a set of patient clusters that demonstrate opportunity as identified by the framework can directly link quality with funding.

Impact of Transformation

The selected QBPs must align with the government's transformational priorities including alignment with the tenets of Ontario's Action Plan for Health Care. In addition, a natural progression and trajectory to assess a QBP's impact on transformation would be to begin to look at other patient cohorts (e.g., paediatric patient populations), impact on the transition of care from acute-inpatient to community care setting, significant changes from historical funding

models/approaches, integrated care models, etc. QBPs with lesser cost impact but a large impact on the transformation agenda may still be a high priority for creation and implementation.

2.4 How will QBPs encourage innovation in health care delivery?

QBP strategy is driven by clinical evidence and best practice recommendations from the Clinical Expert Advisory Groups. The Clinical Expert Advisory Groups are comprised of cross-sectoral, multi-geographic, and multi-disciplinary membership with representation from patients as well. The panel members leverage their clinical experience and knowledge to define the patient populations and recommend best practices.

Once recommended best practices are defined, these practices are used to understand required resource utilization for the QBPs and 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 redesign to improve patient outcomes.

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

QBPs create opportunities for health system change 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 will be in the development of indicators to allow for the evaluation and monitoring of actual practice and support on-going quality improvement.

3.0 Description of Aortic Valve Disease

Describe the Aortic Valve Disease population.

Aortic valve disease (AVD) is a cardiac condition in which the aortic valves are malfunctioning causing an obstruction to 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 aortic stenosis (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 aortic valve replacement (AVR), AVR with coronary artery bypass graft (CABG), and transcatheter aortic valve implantation (TAVI).

[1] Cardiac Care Network of Ontario (CCN). 2013. Ontario Cardiac Services Road Map. Toronto: CCN.

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 PARTNER (Placement of AoRtic TraNscathetER Valve) - Cohort B) trial who were treated medically, the survival at 1 year was only 50%.[2]

Treatment Option:

Surgical aortic valve replacement (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. Surgical aortic valve replacement 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]

Alternatives to Surgical Aortic Valve Surgery:

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 surgical AVR.

2. Balloon Aortic Valvuloplasty

Balloon aortic valvuloplasty (BAV) was considered to be a less invasive and safe alternative to AVR, 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

[2] Leon MB, Smith CR, Mack M, et al. Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery. N Engl J Med 2010;363:1597-1607.

[3] Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease. European Heart Journal 2012;33:2451–2496. doi:10.1093/eurheartj/ehs109

months. Patients treated with BAV alone have shown poor prognosis, with survival rates of 50% at 1 year, 35% at 2 years, and 20% at 3 years. Balloon aortic valvuloplasty, therefore, should not be used as a substitute for AVR in patients who are candidates for surgical AVR.[4]

3. Transcatheter Aortic Valve Implantation or Replacement (TAVI or TAVR)

Given the increased mortality and morbidity of AVR surgery for high-risk patients and the poor long-term results of medical therapy and balloon aortic valvuloplasty, 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.

AVD QBP Inclusion/Exclusion Criteria.

This QBP is for the provision of AVR, AVR with CABG, and TAVI for the surgical and percutaneous replacement of aortic valve in patients with aortic valve disease. Patients with coronary disease undergoing SAVR may be considered for combined SAVR and coronary artery bypass graft surgery (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.

Inclusion Criteria:

- Patients equal to or over 20 years of age;
- Male and female patients and those cases indicated as unknown;
- Ontario-resident reported cases that have been performed within an Ontario hospital (acute facility); and
- Removal reason in the CCN Cardiac Registry as ‘procedure started’ for Isolated AVR, AVR with CABG, TAVI, and valvuloplasty.

Exclusion Criteria:

- Out of hospital interventions;
- Cases with missing procedure date; and
- TAVI valves implanted in sites other than aortic valve.

CCN Cardiac Registry Definition:

General Inclusion:

PATIENT_AGE ≥ 20

AND (cardiacwaitlistentry.AuthorityIssuing='CANON'
OR (cardiacwaitlistentry.AuthorityIssuing=NULL
AND waittimepatient.AuthorityIssuingCardCD='CANON'))
AND cardiacwaitlistentry.FundingSourceCD='H'
AND cardiacwaitlistentry.removaldate > 0
AND cardiacwaitlistentry.RemovalReasonCD='PS'

[4] Holmes DR Jr., Mack MJ, Kaul S, et al. 2012 ACCF/AATS/SCAI/STS expert consensus document on transcatheter aortic valve replacement. J Am Coll Cardiol 2012;59:1-104

Isolated AVR (Aortic Valve Repair/Replacement):

Cardiacofflistingdetails.surgery_aorticvalvesurgery='Y'
AND cardiacofflistingdetails.surgery_bypasssurgery='N'
AND cardiacofflistingdetails.surgery_mitralvalvesurgery='N'
AND cardiacofflistingdetails.surgery_othervalvesurgery='N'
AND cardiacofflistingdetails.tricuspidvalvesurgeryind='N'
AND cardiacofflistingdetails.surgery_AorticSurgeryIND='N'
AND cardiacofflistingdetails.cath_transcathAorticValveInterventionIND='N'

AVR with CABG:

cardiacofflistingdetails.surgery_aorticvalvesurgery='Y'
AND cardiacofflistingdetails.surgery_bypasssurgery='Y'
AND cardiacofflistingdetails.surgery_mitralvalvesurgery='N'
AND cardiacofflistingdetails.surgery_othervalvesurgery='N'
AND cardiacofflistingdetails.tricuspidvalvesurgeryind='N'
AND cardiacofflistingdetails.surgery_AorticSurgeryIND='N'
AND cardiacofflistingdetails.cath_transcathAorticValveInterventionIND='N'

TAVI:

cardiacofflistingdetails.cath_transcathAorticValveInterventionIND='Y'

Valvuloplasty:

Cardiacofflistingdetails.Cath_CatheterBasedValveProcedure='Y'
AND cardiacofflistingdetails.Cath_ValvuloplastyIND='Y'

CIHI DAD/NACRS Definition:

General Inclusion:

Age ≥ 20

AND Ontario Funded cases
Excluding:
Out of hospital interventions

Isolated AVR:

Any intervention is 1HV*
Excluding:
1IJ76*
1HS*
1HT*
1HU*
1HW*
1HV90.GP-XXL
1HV90.GR-XXL

AVR with CABG:

Any intervention is 1IJ76* **AND** another intervention is (1HV*)
Excluding:

1HS*
1HT*
1HU*
1HW*
1HV90.GP-XXL
1HV90.GR-XXL

TAVI:

Any intervention is 1HV90.GP-XXL **OR** 1HV90.GR-XXL
Excluding:

1HS*
1HT*
1HU*
1HW*

Describe the evidence-based rationale for choosing repair of aortic valve disease as a QBP.

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

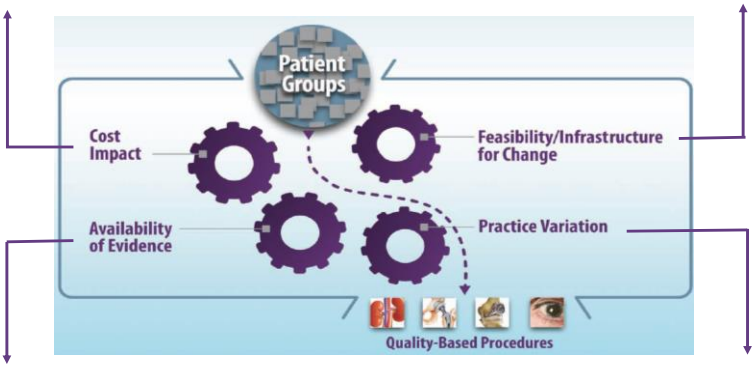
Figure 4: Evidence-based framework for AVD QBP

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.

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.



Availability of Evidence

- 2014 AHA/ACC 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
- "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, OCCI 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 PCI and isolated CABG 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. There 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 CABG procedures. 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 AVR surgery 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.

Describe the application of the evidence-based framework.

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 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.

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 AVR surgery.[5] TAVI outcomes have also been calculated however, not reported publically. For AVR surgery, risk-adjustment models were available and a comparison of mortality rates between cardiac centres was made. Overall, it was found that mortality rates for AVR surgery 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]. 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:

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

	AVR Surgery		TAVI	
Mortality Rate	**Dates**	**Rate**	**Year**	**Rate**
In-Hospital Mortality	October 1, 2008 to September 31, 2011	2.34%	ND	ND
30-Day Mortality		2.03%	January 18, 2007 to March 23, 2012	7.5%
1-Year Mortality	ND	ND		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.

[5] Cardiac Care Network of Ontario (CCN). October 2012. Report on Adult Cardiac Surgery in Ontario. Toronto: CCN.
[6] PARTNER trial (Placement of AoRtic TraNscathetER Valves) was the world's first prospective, randomized and controlled trial to evaluate the effectiveness of TAVI.

This 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 surgical AVR 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 AVR surgery 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.

Describe the key objectives of the aortic valve disease 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 aortic valve disease on the healthcare system;
- Ensure SAVR and TAVI, and related tests are performed appropriately according to recommended guidelines;
- Be accountable to patients with aortic valve disease through public reporting of quality and performance metrics;
- Ensure equitable access to standardized care for the SAVR and TAVI treatment of aortic valve disease across Ontario; and
- Address service gaps and/or need for capacity and infrastructure management to determine future development needs.

How will AVR and TAVI be documented? Is there a need for a new data collection process?

CCN holds the registry for tracking all advanced cardiac procedures in Ontario. Once a patient is referred for a cardiac procedure, their clinical history and existing comorbidities are entered into the Cardiac Registry by the Regional Care Coordinators (RCCCs) and Data Clerks. After the patient receives a procedure, the RCCC or Data Clerk enters all related information into the registry including date of procedure, procedure performed, and specific procedural details. Cardiac procedural utilization is verified monthly by the hospitals and reported by CCN at the local and provincial level.

To standardize documentation and procedural coding, it is recommended that the CCN Cardiac Registry should be used as the source of data for future costing and evaluation. The use of the CCN Cardiac Registry would not require a new data collection process. The registry captures comprehensive information and details of isolated AVR, AVR with CABG and TAVI patient comorbidities, wait times, and procedures. The Cardiac Registry is updated bi-annually which would allow for additional data elements to be collected (e.g., smoking cessation education).

How will clinical documentation change? What are the implications on physician charting on billing and AVD QBP funding?

Currently there are no standardized guidelines or recommendations regarding what information need to be recorded onto patient charts by physicians. This inconsistency has resulted in variability of coding practices for various advanced cardiac procedures and surgeries. With the CCN Cardiac Registry, consistent and granular data is available for accurate coding and review of advanced cardiac procedures in Ontario.

A monthly CCN Cardiac Registry report may be generated to inform costing reconciliation at each healthcare system. Procedural coding should be based on this report to create and maintain consistency in submission process for provincial funding of advanced cardiac procedures and surgeries.

How were the clinicians engaged? Please describe the process for clinical engagement.

CCN convened the Cardiac QBP Expert Panel composed of clinical, technical and health data experts and other stakeholders to support the provincial quality agenda related to the Health System Funding Reform and Quality-Based Procedures strategy. The purpose of the Expert Panel is to develop, support and promote the utilization and implementation of evidence-based best practice clinical care pathways, quality indicators and pricing models for Aortic Valve Disease (AVD) including: SAVR, SAVR with CABG, and TAVI.

The provincial CCN Cardiac Registry and CIHI's Discharge Abstract Database (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 validation webcast that engaged a broader audience.

4.0 Best Practices Guiding the Implementation of AVD QBP

Best Practice – AVD Clinical Pathway:

Best practices 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 (AVR, and AVR with CABG) and non-surgical treatment (TAVI). The pathways include a small volume of aortic valve repairs including those that had a balloon aortic valvuloplasty (BAV) prior to AVR. 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.

Evaluation:

The ACCF/AHA[7] and ESC/EACTS[8] 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 echocardiography (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 valvular heart disease. Echocardiography provides the required information for determination of valve characteristics, etiology, and diagnosis of valvular heart disease. 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 aortic stenosis.

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

Patient selection:

Patient selection for AVR is well outlined by ACCF/AHA and ESC valvular heart disease guidelines for those with aortic stenosis. 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 AVR is determined using surgical risk scores. The most commonly used risk algorithms for cardiac surgery are the STS and EuroSCORE II. Although the STS risk score and EuroSCORE II provide information concerning short-term operative risks and benefits, they are not able to predict symptom resolution, quality-

[7] Nishimura RA, Otto CM, Bonow RO, et al. AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014; 129:1-235.
[8] Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease. European Heart Journal 2012;33:2451–2496. doi:10.1093/eurheartj/ehs109.

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 AVR may be technically feasible, since age-related and comorbid conditions commonly exist in this group.

Education:

Aortic valve disease 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.[9]

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 and family.

Goals of care:

The interprofessional team must discuss the goals of care with patient and family prior to any procedure or at patient's admission to hospital.

Medical Therapy:

Guideline-directed medical therapy is recommended for other medical conditions that pose additional risk to patients with AS.[10]

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.

Current Treatment Options for Aortic Valve Disease:

1. Surgical Aortic Valve Replacement (SAVR)

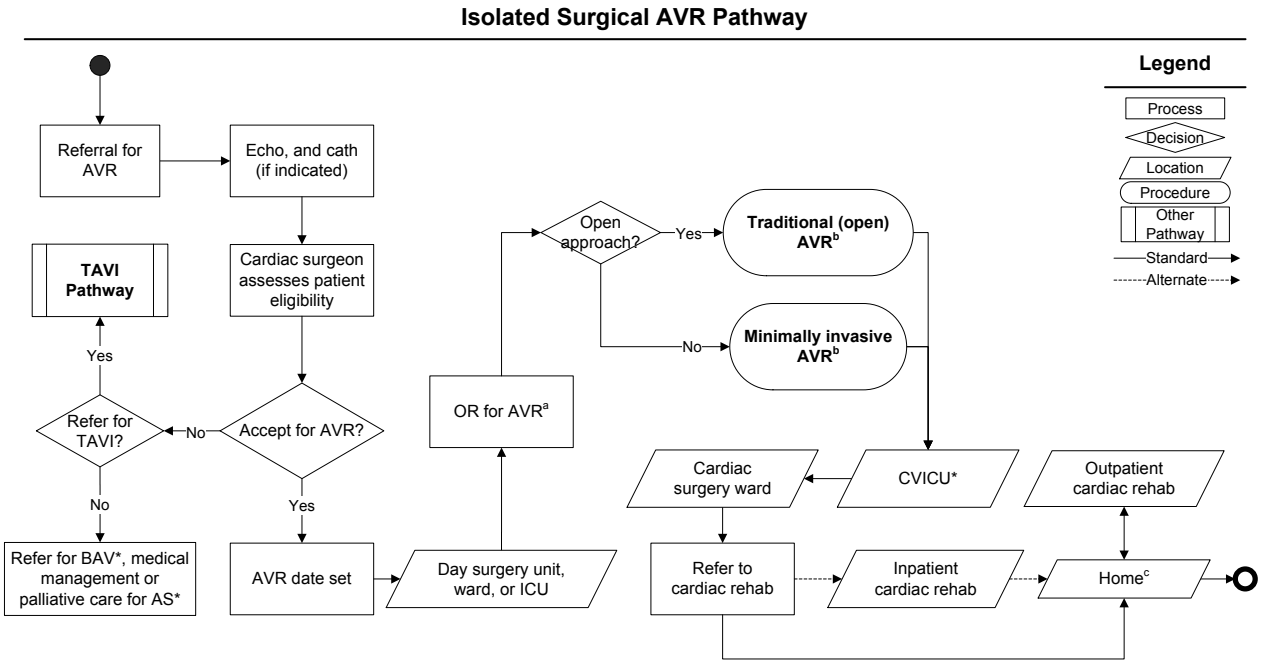
Information from the STS National Database shows that the operative mortality for isolated SAVR has declined from 3.4% in 2002 to 2.6% today. Many SAVR patients are older, with other

[9] Choosing Wisely Canada (2014). Retrieved from http://www.choosingwiselycanada.org/about/what-is-cwc/
[10] Nishimura RA, Otto CM, Bonow RO, et al. AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014; 129:1-235.

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.[11]

Not all patients referred for SAVR undergo as extensive diagnostic imaging and testing as TAVI candidates. The evaluation, management and treatment of patients with severe or complex aortic valve disease are best achieved by a Heart Team which is composed primarily of a cardiologist, cardiac surgeon, and structural interventionalist (i.e. valve specialist). [12]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.

Figure 5: Pathway for Isolated SAVR



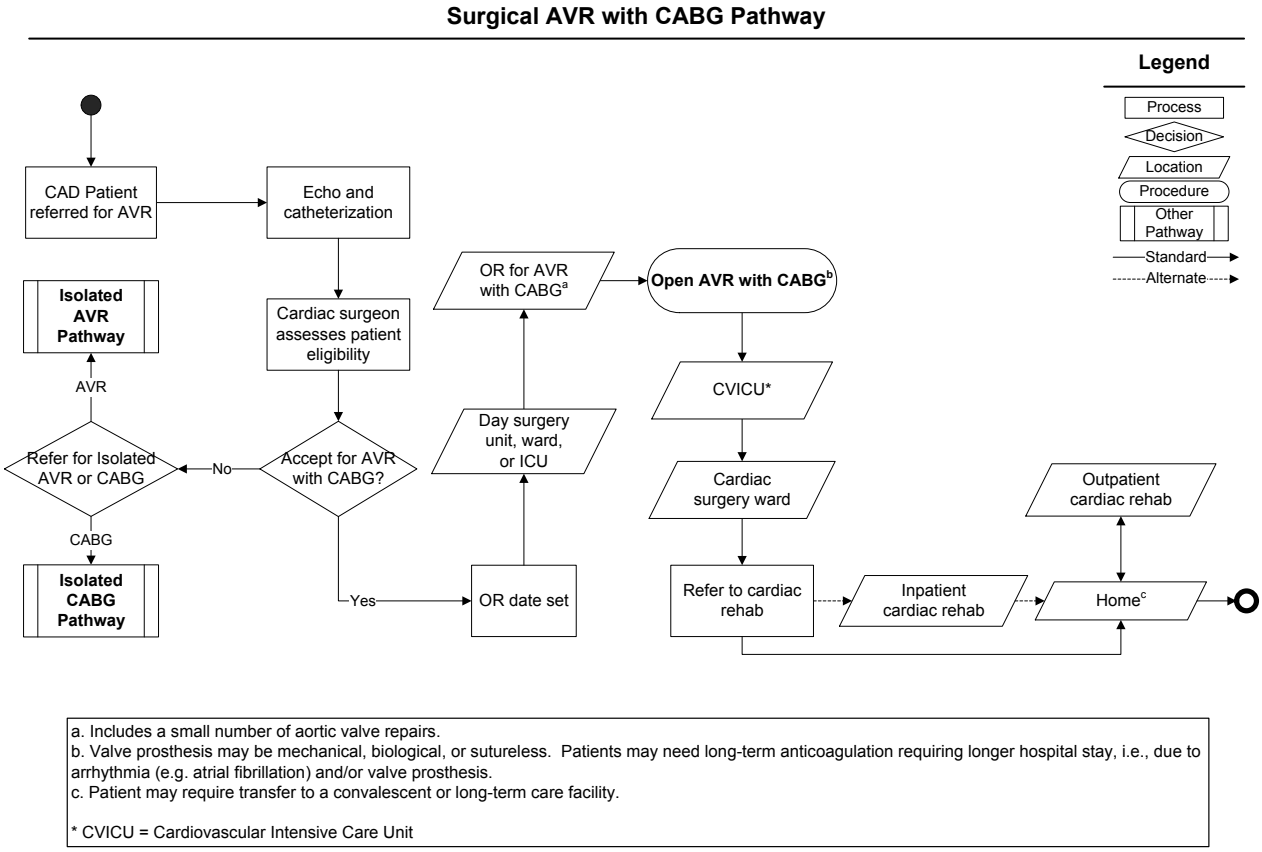
a. Includes a small number of aortic valve repairs.
b. Valve prosthesis may be mechanical, biological, or sutureless. Patients may need long-term anticoagulation requiring longer hospital stay, i.e., due to arrhythmia (e.g. atrial fibrillation) and/or valve prosthesis.
c. Patient may require transfer to a convalescent or long-term care facility.

* AS = Aortic Stenosis; BAV = Balloon Aortic Valvuloplasty; CVICU = Cardiovascular Intensive Care Unit

[11] Harris RS, Yan TD, Black D, et al. Outcomes of Surgical Aortic Valve Replacement in Octogenarians. Heart, Lung and Circulation 2013;22(8):618–626.
[12] Nishimura RA, Otto CM, Bonow RO, et al. AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2014; 129:1-235.

Patients with coronary artery disease undergoing SAVR may also have coronary artery bypass graft (CABG) surgery at the same time (See Figure 6). Guidelines recommend that individual clinical judgement is made taking into consideration patient physical and clinical factors when determining the timing of surgical treatment for AVD and CAD.[13]

Figure 6: Pathway for SAVR with CABG



a. Includes a small number of aortic valve repairs.
b. Valve prosthesis may be mechanical, biological, or sutureless. Patients may need long-term anticoagulation requiring longer hospital stay, i.e., due to arrhythmia (e.g. atrial fibrillation) and/or valve prosthesis.
c. Patient may require transfer to a convalescent or long-term care facility.

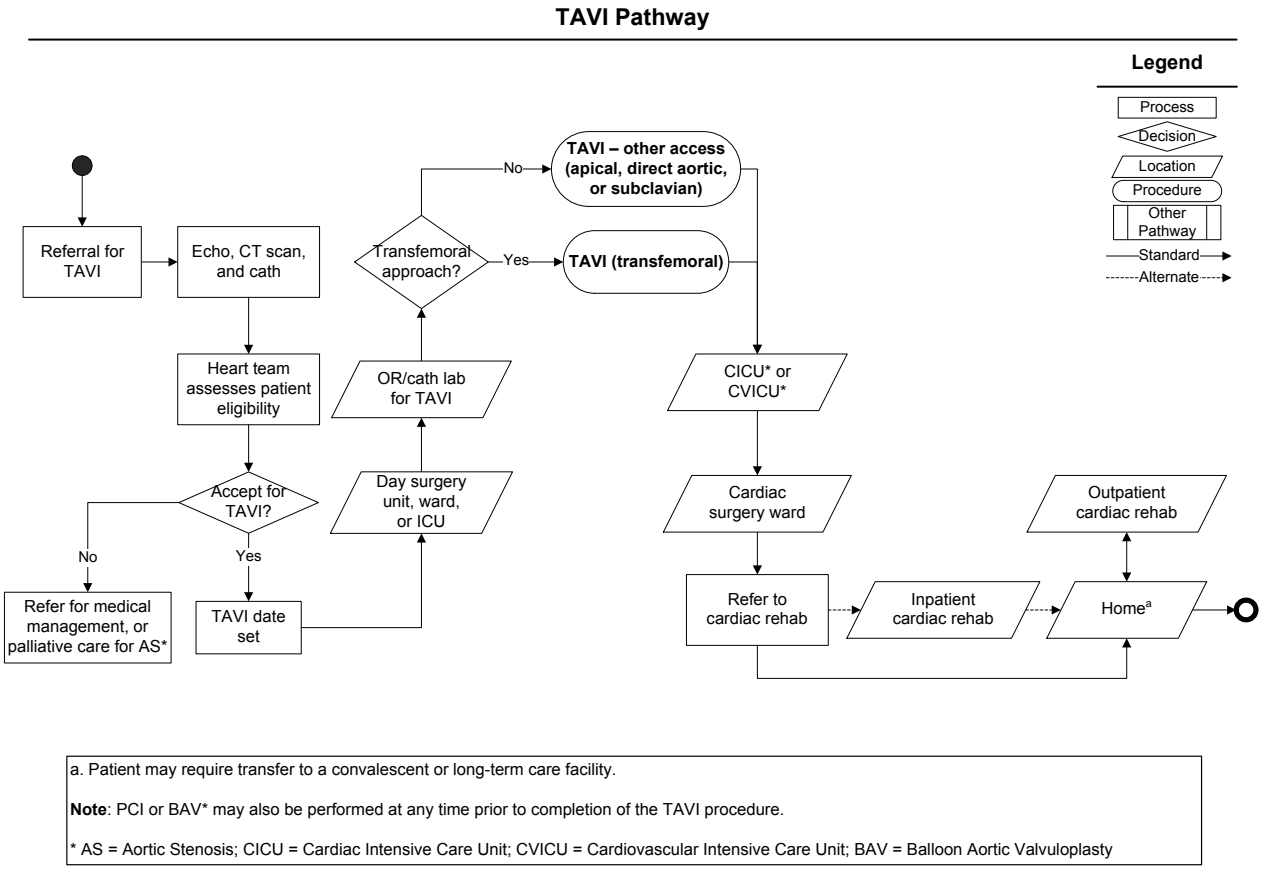
* CVICU = Cardiovascular Intensive Care Unit

2. 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 (See Figure 7 for TAVI pathway).

[13] Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease. European Heart Journal 2012;33:2451–2496. doi:10.1093/eurheartj/ehs109.

Figure 7: Pathway for TAVI



a. Patient may require transfer to a convalescent or long-term care facility.

Note: PCI or BAV* may also be performed at any time prior to completion of the TAVI procedure.

* AS = Aortic Stenosis; CICU = Cardiac Intensive Care Unit; CVICU = Cardiovascular Intensive Care Unit; BAV = Balloon Aortic Valvuloplasty

Clinical Decision Tree for Patients with Aortic Stenosis[14]: SAVR or TAVI

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.).

   (Conditional Recommendation, Low-Quality Evidence).

3. Transfemoral TAVI is recommended if:
   a. The risk of open heart surgery is prohibitive;

[14] Webb J, Rodés-Cabau J, Fremes S, et al. Transcatheter Aortic Valve Implantation: A Canadian Cardiovascular Society Position Statement. Canadian Journal of Cardiology, 28 (2012); 520–528.

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.

Pre-procedural or surgical care:

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

- Informed consent;
- For SAVR, assess patient suitability for autologous blood donation 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. INR), complete blood count, electrolytes, renal profile including 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. $P2Y_{12}$ receptor inhibitors, glycoprotein IIb/IIIa inhibitors).

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.[15]

Intra-procedure care:

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

- Accreditation Canada International[16];
- Operating Room Nurses Association of Canada (ORNAC)[17];
- Association of Operating Room Nurses (AORN)[18]; and
- Provincial Infectious Diseases Advisory Committee (PIDAC)[19].

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, and electrolytes investigation typically done in conjunction with activated clotting time (ACT) monitoring by anesthesia or perfusion;
- Trans-esophageal Echocardiogram (TEE);

[15] Hillis LD, Smith PK, Anderson JL, et al. 2011 ACCF/AHA guideline for coronary artery bypass graft surgery: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2011;124:e652–e735.
[16] Accreditation Canada International. QMentum International: Operating Room Standards.
[17] Operating Room Nurses Association of Canada (ORNAC). Standards for Perioperative Registered Nursing Practice 11th Edition, April 2013.
[18] Association of periOperative Registered Nurses (AORN). 2014 Edition Perioperative Standards and Recommended Practices. AORN. AORN, Inc.
[19] Provincial Infectious Diseases Advisory Committee (PIDAC). Routine Practices and Additional Precautions in All Health Care Settings, 3rd edition. November 2012.

- Intra-aortic balloon pump (IABP), when indicated;
- Access to cardio-pulmonary bypass machine;
- Acess to point-of-care testing device for ACT monitoring; and
- Access to renal replacement therapy.

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.
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.

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.[20] 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.

[20] Preen D, Bailey BES, Wright A, et al. Effects of a multidisciplinary, post-discharge continuance of care intervention on quality of life, discharge satisfaction, and hospital length of stay: a randomized controlled trial. International Journal for Quality in Health Care 2005; 17:43-51. 10.1093/intqhc/mzi002.

Systematic and viable links to community programs with defined documentation and communication should occur before patient's discharge from hospital. A systematic referral is vital for cardiac rehabilitation in improving patient's participation in supervised exercise programs.[21] In order for patients to achieve optimal benefit from exercise programs, cardiac rehabilitation should commence within 30 days of hospital discharge.[22] Cardiac rehabilitation is recommended for patients after surgical treatment of valvular heart disease.[23] Similarly, smoking cessation in-hospital education and cessation therapy should be offered to all identified smokers among AVD patients particularly those with concomitant CAD.

[21] Grace SL, Chessex C, Arthur H, et al. Systematizing Inpatient Referral to Cardiac Rehabilitation: A joint policy position of the Canadian Association of Cardiac Rehabilitation and Canadian Cardiovascular Society. Canadian Journal of Cardiology 2011;27:192-199.

[22] Dafoe W, Arthur H, Stokes H, et al. for the Canadian Cardiovascular Society Access to Care Working Group on Cardiac Rehabilitation. Universal access: But when? Treating the right patient at the right time: Access to cardiac rehabilitation. Can J Cardiol 2006;22(11):905-911.

[23] Butchart EG, Gohlke-Ba¨rwolf C, Antunes MJ, et al. on behalf of the Working Groups on Valvular Heart Disease, Thrombosis, and Cardiac Rehabilitation and Exercise Physiology, European Society of Cardiology. Recommendations for the management of patients after heart valve surgery. European Heart Journal 2005;26:2463–2471.

5.0 Implementation of best practices

How should the best practices be implemented to ensure standardized and optimal patient care delivery?

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.

Describe data management implications.

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 Cardiac 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 bi-annually to reflect accurate collection of recommended procedural details, quality indicators, and outcome measures.

6.0 What does it mean for interprofessional teams?

Will Aortic Valve Disease (AVD) QBP have any implication on 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 World Health Organization 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."[24]

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.

[24] World Health Organization (2010). Framework for action on interprofessional education and collaborative practice. Geneva, Switzerland: World Health Organization.

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 AVR.

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 TAVIs being completed in Ontario has been steadily increasing over the past five fiscal years. It is expected that TAVI volumes will continue to increase after implementation of QBP-based funding. Currently, TAVI is reserved for patients that are at high-risk for conventional SAVR. Among this cohort of TAVI-eligible patients there are many patients that are currently considered too high-risk even for TAVI. It is expected that as TAVI technology progresses, in the future, this procedure will be offered to patients who are currently deemed too high-risk for TAVI.

It is doubtful that new TAVI centres will be required in Ontario to support the increase in TAVI procedures in the near future, however there are currently ten TAVI programs in Ontario with only six receiving funding from the MOHLTC. The remaining four centres will most likely require official funding to continue to support their TAVI programs.

Implementation of QBP-based funding in Ontario does have the potential to destabilize current cardiac programs. It is expected that funding for SAVR procedures will be reduced under this new funding model and careful monitoring of current programs will be required. The current recommendation for TAVI usage in Ontario is that it be restricted to patients who are considered too high-risk to undergo conventional AVR surgery. Government policy makers and hospital administrators should work together with clinicians to ensure that funding is adequate to support the clinical work-up that goes into this decision making process and that patients continue to receive the most appropriate procedures and the highest quality of care.

8.0 Performance evaluation and feedback

An integrated scorecard for AVD will be developed to allow the MOHLTC 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.

The Cardiac Care Network of 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 AVR surgery 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 surgical AVR 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.

Quality Indicators for Immediate Implementation

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 only).*
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.

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 care.

Proposed Quality Indicators for Future Development

1. Percentage of cardiac procedures completed within the recommended wait time.
2. Rate of vascular access site complications (for TAVI only).
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.

In introducing the QBPs the MOHLTC 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; and
- 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 4 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?	• Proportion of QBPs that improved outcomes • Proportion of QBPs that reduced variation in outcome • 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?	• Proportion of QBPs that reduced variation in utilization • Proportion of (relevant) QBPs that saw a substitution from inpatient to outpatient/day surgery • Proportion of (relevant) QBPs that saw a substitution to less invasive procedures • Increased rate of patients being involved in treatment decision • 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?	• Reduction in 30-day readmissions rate (if relevant) • Improved access to appropriate primary and community care including for example psychosocial support (e.g., personal, family, financial, employment and/or social needs) • Coordination of care (TBD) • 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?	• Actual costs vs. QBP price
Access	Are those in need of care able to access services when needed?	• Increase in wait times for QBPs/for specific populations for QBP • Increase in wait times for other procedures • Increase in distance patients have to travel to receive the appropriate care related to the QBP • Proportion of providers with a significant change in resource intensity weights (RIW)

Quality Domain	What is being measured?	Key provincial indicators
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)	• Increased rate of patients being involved in treatment decision • Coordination of care (TBD) • 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

The Cardiac Care Network, in collaboration with the QBP expert panel for aortic valve disease, will continue to provide support and ongoing education to the provincial cardiac centres related to these quality-based procedures. 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 MOHLTC, 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

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.

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.

Why are Cardiac QBP definitions from both the CCN Cardiac Registry and CIHI included?
Both definitions are included as reference for volume reconciliation and verification by hospitals.

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
Malik, Dr. Paul	Interventional Cardiologist Co-director, TAVI Program, KGH Assistant Professor of Medicine, Queen's University Cardiovascular Curriculum Chair, Queen's Medical School	Kingston General Hospital
Payne, Dr. Darrin	Cardiac Surgeon Assistant Professor, Queen's University	Kingston General Hospital
Radhakrishnan, Dr. Sam	Interventional Cardiologist Director, Cardiac Catheterization Labs Schulich Heart Centre Assistant Professor, Department of Medicine University of Toronto	Sunnybrook Health Sciences Centre
Ouzounian, Dr. Maral	Cardiovascular Surgeon Assistant Professor of Surgery, University of Toronto	University Health Network
Teoh, Dr. Kevin	Cardiac Surgeon Adjunct Assistant Professor, McMaster University	Southlake Regional Health Centre
Velianou, Dr. James	Interventional Cardiologist Director, Cardiac Care Unit Co-Director, Catheterization Laboratory Associate Professor of Medicine, McMaster University	Hamilton Health Sciences Centre, General Campus
Wijeysundera, Dr. Harindra	Interventional Cardiologist Schulich Heart Centre, Sunnybrook Health Sciences Centre Scientist, Sunnybrook Research Institute (SRI) Assistant Professor, Dept. of Medicine & Institute of Health Policy, Management and Evaluation, University of Toronto Adjunct Scientist, Institute for Clinical Evaluative Sciences (ICES)	Sunnybrook Health Sciences Centre

Technical		
Chen, Ms. Jane	Manager, Case Costing and Activity Reporting	University Health Network
Gerson, Mr. Darren	Director, Performance Evaluation Services	Rouge Valley Health System
Lee, Mr. Gary	Manager, Decision Support	Sunnybrook Health Sciences Centre
Orescanin, Ms. Karen	Manager, Decision Support, Corporate Reporting	Hamilton Health Sciences Centre
Travassos, Ms. Filomena	Manager, Decision Support	Trillium Health Partners
Welham, Ms. Linda	Professional Resources, Decision Support, Case Costing	Southlake Regional Health Centre
Administrative		
Gray, Ms. Debbie	Administrative Director, Critical Care	Health Sciences North
Newman, Ms. Erone	Program Director, Heart and Vascular Program	St. Michael's Hospital
Nieminen, Mr. Tomi	Director, Decision Support Services	St. Michael's Hospital
Petersen, Mr. Ben	Vice President and Chief Financial Officer	Health Sciences North
Sherrard, Ms. Heather	Vice President, Clinical Services	University of Ottawa Heart Institute
Young, Mr. Michael	Executive Vice President, Corporate	Sunnybrook Health Sciences Centre
CCN STAFF		
Forsey, Anne	Director, Clinical Services	Cardiac Care Network
Kutty, Sudha	Director, Knowledge Management	Cardiac Care Network
Braga, Vevien	Senior Clinical Lead, QBPs	Cardiac Care Network
Li, Lindsay	Senior Business Analyst	Cardiac Care Network
Pardhan, Anar	Business Development Analyst	Cardiac Care Network
Lian, Dana	Business Development Analyst	Cardiac Care Network

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