Heart Valve Disease in Canada: Recommended Components for a National Strategy

White Paper from National Policy Roundtable

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INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

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Significant content contribution was provided by all the Roundtable participants who are outlined in Appendix B.

Inquiry:

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Executive Summary

This report is the result of a national consultation and roundtable deliberation conducted by the Institute of Health Economics to support the development of a National Strategy for Heart Valve Disease in Canada. Two virtual policy engagements with clinical leaders, patients and health system managers were conducted in November 2021. These workshops identified 9 thematic areas and developed associated recommendations for action under each theme.

Brief Background on Heart Valve Disease

The heart consists of four chambers: two atria (upper chambers) and two ventricles (lower chambers), and four valves (one for each chamber): aortic valve, mitral valve, tricuspid valve, and pulmonary valve. The mitral valve and tricuspid valve are located between the atria and the ventricles. The aortic valve and pulmonic valve are located between the ventricles and the major blood vessels leaving the heart. The valves keep blood moving through the heart in the right direction and prevent the backward flow of blood.

Heart valve structure



Stenosis

When the valves opening becomes narrowed, it limits the flow of blood out of the ventricles or atria. The heart is forced to pump blood with increased force to move blood through the narrowed or stiff (stenotic valves).

Regurgitation

When the valve(s) do not close completely, it causes blood to flow backward through the valve. This reduces forward blood flow and can lead to volume overload in the heart.

Heart valve disease (HVD), also known as valvular heart disease (VHD), occurs when any of the four valves either cannot open properly to let blood flow through (stenosis) or cannot close properly to prevent backflow of the blood (regurgitation). HVD can cause stenosis, regurgitation, or combination of the two in any of the four valves. It can also affect more than one heart valve (i.e., multiple heart valve disease). HVD can be a serious disease; left untreated, advanced valve disease can cause heart failure, stroke, arrythmia, blood clots, or death *i*ncluding sudden cardiac arrest.



Key facts

- The incidence of heart valve disease (HVD) is markedly increasing with the aging of the population and should be considered as one of the next epidemics affecting millions of people worldwide.
- Heart valve conditions are serious conditions and can be fatal if left untreated but are eminently and increasingly treatable especially if detected early.
- Innovation in treatments as well as detection and management to address gaps in care are an urgent priority.
- It is estimated that 2.5 % of the population has heart valve disease increasing significantly after the age of 65 reaching 13% after the age of 75.
- Aortic stenosis and mitral regurgitation are the two most common HVDs.
- In 2040 Canada will have an estimated 1.5 million people over 65 with HVD.
- There is low public awareness of health valve disease. For examples only 3% of Canadians over 60 are aware of aortic stenosis, the most common type of heart valve disease.
- Between 2007 and 2017, there was a 68% increase in the number of hospitalizations for heart valve disease in Canada.

Heart Valve Disease (HVD)

HVD are cardiac defects often and increasingly linked to functional decline and population ageing that demand repair and/or replacement of heart valves such as aortic stenosis, mitral valve regurgitation and tricuspid regurgitation.



In **2040** Canada will have an estimated **1.5 million people** over 65 with **HVD**.

This figure has been extrapolated based on projected demographic data from Statistics Canada and the burden of Structural Heart Diseases provided in the Ox/ALVE Population Cohort Study.





Heart Valve Disease Burden

* These figures have been extrapolated based on projected demographic data from Statistics Canada and the burden of heart valve disease provided in the OxVALVE Population

Heart valve disease is a significant and important part of cardiovascular disease yet often does not get as much attention as heart attack, heart failure or stroke although it may be a significant factor responsible for such complications. Heart valve disease is multifaceted and very complex, and is an umbrella term includes a wide variety of conditions affecting all the different valves of the heart. Valve disease treatment plans can be complex, with many factors determining who might be a candidate for medical therapy or valve repair/replacement.

One of the greatest challenges still remains early detection of valve disease, which is required to stratify patients quickly and effectively, to allow tailoring of the correct treatment or management plan to the patient. It is important to remember the term heart valve disease include a menagerie of complex cardiovascular pathologies and it is only through incorporating multidisciplinary approaches that the system will be able to address the variety of different heart valve diseases effectively.

This is an exciting time for those involved with heart valve disease. While there is still more research needed in the causes and potential prevention approaches, there have been significant advancements in treatment options. The availability of non-surgical valve intervention reduces the barriers for older patients to enhanced life expectancy and quality of life. There are also increasingly promising approaches in detection technologies that might allow earlier identification by patients and their primary care providers. Of course, many of the tools to address this issue are already available and just need to be organized and managed to significantly improve the detection, diagnosis, treatment and ongoing management for Canadian patients.



Key Points

- Incidence of heart valve disease (HVD) is markedly increasing with aging of the population and should be considered as one of the next epidemics affecting millions of people worldwide. Thus, HVD will be an increasing concern for the health system and addressing gaps is an urgent priority.
- Heart valve conditions are serious conditions and can be fatal if left untreated but are eminently and increasingly treatable especially if detected early.
- Patients with HVD are often underdiagnosed, undertreated and referred for care too late in the course of the disease. HVD can cause complications such as heart failure and stroke.
- Not providing timely and equitable access (i.e. *age, income, gender, geography*) to diagnosis and treatment is responsible for an excess mortality and morbidity not restored by any intervention and comes with significant costs to society, communities and the health system.
- Greater awareness is needed by patients, providers and health system decision-makers of how heart valve disease develops, is detected and about the new approaches to manage treatments on what are often older patients with significant co-morbidities.
- Symptoms can mimic general signs of aging and can often be ignored by patients and by health providers. There are long periods of silent progression with no symptoms.
- Early detection is critical through regular and standardized clinical assessment, cardiac auscultation and ensuring access to quality assured echocardiography and other diagnostics.
- Evidence-informed care pathways have been developed and are generally accepted and adherence should be monitored. This is especially important in detection and in post-procedural care. A systemic approach to regular cardiac consultation is needed.
- Systems of care should include standardized referral pathways with full treatment options and multidisciplinary clinics ensuring ongoing assessment and addressing not only clinical but psychosocial needs.
- Greater attention to shared decision-making between patients, families and providers is increasingly important at all stages of care to ensure options are understood and patient preferences are honored.
- Increasingly there are new technologies, not only in less invasive treatments but also in digital tools for detection. The low risk and high tolerability of new procedures are enabling them to be undertaken earlier in disease progression.
- Uptake of new technologies is slow and it has been suboptimal in terms of moving to being consistently used.
- Funding models are often either global budgets or some limited procedure-based allocations which does not allow natural evolution of practices through appropriate steering in choice of intervention informed by best clinical judgement and patient preference.
- Investment in research is needed to ensure data driven service planning, national and international comparative surveillance and the development of new prevention approaches which only can come with early detection.



Next Steps:

In an effort to address gaps in HVD care in Canada, the Canadian Cardiovascular Society has formed a Heart Valve Disease Strategy Working Group. This working group will provide a mechanism for stakeholders with a shared common interest to come together and work towards transforming the care for individuals living with HVD in Canada. The goals and priorities for that initiative will be informed by this report.



Issues Identified for National Strategy

The following issues were identified in roundtable discussion





The Roundtable identified the following High Level Goals related to each Issue Category

Issues		High Level Goal Statement	
Continuum of Care Issues	Awareness & Education	Patients, health-care providers, governments and the general public are aware and educated on: a) what HVD is, b) the burden caused by HVD on patients, families, and society and c) best practice guidance to detect and manage heart valve disease along the patient journey.	
	Detection, Screening, Diagnosis & Monitoring through Clinical Surveillance	HVD is detected and diagnosed as early as possible regardless of gender, age, ethnicity or where people live, and there is consistent and ongoing monitoring of HVD through clinical surveillance.	
	Management& Treatment	Patients receive and participate in individualized, appropriate, equitable and timely access to evidence-based interventions/services.	
	Post-Intervention Monitoring & Management	Patients receive appropriate monitoring and detection of any progression and/or complications after intervention and are empowered to take ongoing control over management of their illness.	
Systemic Policy Issues	Quality & Access	There is equitable access to quality detection, diagnosis and appropriate ongoing treatment of heart valve disease for all Canadians regardless of gender, age, where they live or specific personal characteristics or circumstances.	
	Organization of Care	The system is organized and resourced and providers coordinated to optimally support patients with heart valve disease from population-based detection to management/intervention through to ongoing monitoring and support.	
	Innovation & Technology	New innovations in care should be rapidly incorporated first into trial use to allow the evidence on costs and outcomes (including patient- centred outcomes) to be gathered and when and if value is demonstrated have a clear pathway to move to standard care.	
	Funding	Funding models should be more nimble to allow for clinician and patient judgements to be incorporated in treatment choices along the patient journey, incorporating evidence-based innovations in clinical care while ensuring ongoing system sustainability, and affordability.	
	Data and Research	Key knowledge gaps to advance heart valve disease prevention, diagnosis and treatment including medical therapy in Canada are addressed through public and private research funders.	

The participants then articulated key actions to work towards each goal. These are outlined in the following pages.



Awareness and Education

Patients, health-care providers, governments and the general public are aware and educated on: a) what HVD is, b) the burden caused by HVD on patients, families, and society and c) best practice guidance to detect and manage heart valve disease along the patient journey.

- A National Awareness campaign should be conducted to raise public awareness on what HVD is, its symptoms, prevalence, burden and ongoing development of options to treat, manage and frequently cure. This comprehensive campaign should be tailored for a variety of target audiences (general public, health care providers, policy makers, etc.).
- An awareness and education program on HVD should be established for primary care providers and community cardiologists, including knowledge on new innovative treatment options. This should include HVD competencies curriculum for medical schools, other primary care provider training and postgraduate health professional training.
- Support and fund HVD patients' organization to allow planning for multi-year programs where possible looking for alignment and collaboration with other disease organizations.
- Federal and Provincial level advocacy programs should be coordinated and aligned to support awareness, screening and educations programs across Canada (i.e. special events, recruitment of senior political champions, patient ambassadors). (Sufficient checks and balances are in place to ensure demonstrated independence from industry marketing efforts).
- Build infrastructure to establish National Report Card and report on incidence, identification of diagnosis gaps, treatment access, and outcomes of interventions.



Issue

Detection, Screening, Diagnosis & Monitoring through Clinical Surveillance

HVD is detected and diagnosed as early as possible regardless of gender, age, ethnicity or where people live, and there is consistent and ongoing monitoring of HVD through clinical surveillance.

- Support should be provided to national and provincial efforts to improve access to primary health care providers.
- Align with national primary health care strategies to ensure HVD is included as a standard component of regular comprehensive screening and documentation done at a primary health care (PHC) setting.
- Canadians who are suspected to have HVD have access to specialist assessment and high-quality diagnostic testing provided in alignment with international/national guidelines.
- Diagnostic services should be organized around population needs, not provider concentration. (initial step would be mapping of echocardiogram access across the country, and identifying gaps).
- Explicit Guidance/standards should be established on wait times for referral based on best emerging evidence and regularly reviewed.
- A system capacity plan for distributed high quality echocardiography should be developed by provincial governments and professional associations – with focus on increasing community access.
- After detection of heart valve disease all patients should receive appropriate ongoing surveillance and lifetime management from a dedicated structure/clinic including physicians with specific knowledge in VHD that ensures they have a consistent point of contact to address and evaluate symptom changes.
- Evidence-based tools and checklists to support shared decision making between patients with HVD and their families, primary care providers and specialists should be developed and be widely available. This should include ongoing knowledge transfer support and evaluation.



Management & Treatment

Patients receive and participate in individualized, appropriate, equitable and timely access to evidence-based interventions/services.

- Federal and provincial governments should ensure that all Canadians with HVD receive equitable and timely access to appropriate care and treatment options. (be they surgery, transcatheter interventions or medical management including palliative care.).
- An environmental scan should be conducted on existing treatment options in the various centres across Canada, identifying gaps and potential areas for additional investments.
- Ensure there are dedicated heart valve programs that either offer a full spectrum of care or have an established relationship and/or network with other centres which provide access to evidence-based treatment options. (hub and satellite model)
- Decrease waiting time between referral and treatment with clear national reporting that includes audit and follow up.
- Formal guidance for treatment choice discussions should be developed incorporating key decision points for incorporation of patient preferences. This should include some dedicate knowledge transfer support and evaluation.



Recommendations

Issue

Post-Intervention Monitoring & Management

Patients receive appropriate monitoring and detection of any progression and/or complications after intervention and are empowered to take ongoing control over management of their illness.

- Establish a standardized follow-up plan at discharge for patients, primary care providers and cardiologists with monitoring following established international standards in terms of regular diagnostic tests and include incorporation of psychosocial and other supports.
- Monitor to ensure that appropriate imaging strategies post intervention, including echocardiograms are provided and report mid and long-term outcomes that follow national and international practices.
- Immediate discharge planning should recognize potential value of ongoing innovations in practice approaches that support safe and earlier discharge, mobilization and support transitions in care.
- Ensure that ongoing management includes assessments and management of comorbidities and cardiovascular risk factors, management of anticoagulation when needed and endocarditis prophylaxis.
- Improved access and clear guidance should be developed for patients requiring end-of-life supports and care teams. (building off work done in heart failure).



Issue

Quality & Access

There is equitable access to quality detection, diagnosis and appropriate ongoing treatment of heart valve disease for all Canadians regardless of gender, age, where they live or specific personal characteristics or circumstances.

- Standardized outcome indicators should be established and which are regularly reported building on work from the International Consortium of Health Outcome Measures (ICHOM).
- Conduct environmental scan to understand where services are located and where gaps are including documentation of best practice examples of Canadian multi-centre cooperation.
- Codify and publicly report wait times standards for referrals and treatment based on consensus guidelines.
- Conduct assessment of specific issues for access for Indigenous and rural populations to detect, diagnosis and treat HVD (in collaboration with indigenous researcher/organization).
- Develop specific guidance related to addressing discrimination by clinicians as well as patient or local community self-discrimination in terms of appropriate and reasonable access to care.
- Model incidence of HVD and capacity needs in workforce, physical infrastructure and resources for 5,10 and 20 years. (this will be key to inform strategy development).
- Insure wider geographical access to echocardiography possibly through innovative solutions including virtual care.



Recommendations

Issue

Organization of Care

The system is organized and resourced and providers coordinated to optimally support patients with heart valve disease from population-based detection to management/intervention through to ongoing monitoring and support.

- Define the minimum composition and role of the health care provider(s) / heart team responsible for shared decision making at the time of intervention and the role and composition of the dedicated team responsible for clinical surveillance and ongoing monitoring post intervention.
- Ensure there is a coordinated and cooperative approach across specialities for the most effective clinical management by members of the heart team.
- A variety of hub and spoke models for configuring care should be explored and tailored to regional circumstances that ensure referral pathways are clear, treatment is guideline directed, programs are cost-effective and centres are resourced to address demand in an equitable way across Canada.
- Explore future models for integrated heart valve clinics (combining core supports with other programs/specialities). (note: likely challenging to continue proliferations of sub-specialized clinics).
- Establish and use evidence-based guidelines to ensure care pathways support appropriate referrals patterns for all related procedures and report on achievements.
- Identify and share promising local practices that demonstrate better resource use and optimal care pathways in an effort to inform broader system improvements and enhancements.
- Heart valve disease programs should evaluate potential learnings from program changes during recent pandemic and plan for future contingencies where restricted acute care access may be required (i.e accelerating virtual care; potential triage issues, etc).



Recommendations

Issue

Innovation & Technology

New innovations in care should be rapidly incorporated first into trial use to allow the evidence on costs and outcomes (including patient-centred outcomes) to be gathered and when and if value is demonstrated have a clear pathway to move to standard care.

- Health Canada should be encouraged to become increasingly more efficient in approval of medical devices and diagnostic technologies with benchmarking against peers. The case for heart valve technologies should be formally presented.
- Monitor and report on the use of new technologies/procedures in Canada (as TVT registry in the USA) and compare both use and outcomes to peer jurisdictions highlighting where procedures have become routine standard of care and describing key differences across Canada.
- Work with Health Canada, technology assessment bodies and system funders (provinces) to leverage the HVD infrastructure to use real-world evidence to advance regulatory and funding decisions.
- Identify avenues for heart valve disease to raise its profile in major forums as a potential area with readiness for new regulatory and reimbursement approaches in trial use programs being explored with new technology.
- Medical device manufacturers and related clinical specialities should have increased engagement with health technology assessment bodies and health system funder to ensure appropriate data is made available to accelerate approval and reimbursement.
- Model incidence of HVD and capacity needs in workforce, physical infrastructure and resources for 5, 10, and 20 years. (This will be key to inform strategy development).
- Identify new funding models to allow early trial development and funding through coverage with evidence development or research-oriented market access programs.
- There should be rigorous evidence-based assessment processes and pathways for facilitating integration of digital and remote technologies into diagnostic and detection phase, including home and community use.



Issue

Funding

Funding models should be more nimble to allow for clinician and patient judgements to be incorporated in treatment choices along the patient journey, incorporating evidence-based innovations in clinical care while ensuring ongoing system sustainability, and affordability.

- Federal and Provincial governments and health authorities should explore innovative funding models (i.e. condition-based rather than procedure-based funding models and/or bundled payments to allow maximum benefit to system value, and flexibility for clinical judgement and cross-investment across silo budgets. (Heart valve working group should present options for consideration).
- Heart valve disease clinicians and administrators should ensure they explore efficiencies in health valve disease care delivery in their local context especially through potential collaborations with other heart disease programs and find opportunities to share those learnings.
- Health authorities should pursue innovative procurement approaches with medical device manufacturers to support optimal technology diffusion. These approaches should consider the total cost of episodes of care.
- Provincial governments should support the ongoing integration of digital tools such as digital stethoscopes and handheld ultrasound to aid in detection of HVD in primary care settings.
- Federal and provincial government should invest in research to advance the research goal: "Key knowledge gaps to advance heart valve disease prevention, diagnosis and treatment in Canada are addressed through public and private research funders."



Issue

Goa

Data and Research

Key knowledge gaps to advance heart valve disease prevention, diagnosis and treatment including medical therapy in Canada are addressed through public and private research funders.

- Building off of international work, a Heart Valve Research Priorities consensus outlining key gaps in knowledge to inform health policy management and research investments specific to the Canadian system and context is created and endorsed by key partners.
- Invest in building the infrastructure to support national data gathering and the establishment of National Report Card to gather data and report on incidence of HVD, treatment access and identification of diagnosis gaps, ongoing surveillance of comparative costs and outcomes, capacity and structures between provinces and countries. Minimum priority data points should be identified to inform decision-makers.
- Create initiative targeted to promote both basic and clinical research in HVD and to empower the next generation of health researchers in this area (collaboration with CIHR/Industry partners and Heart and Stroke Foundation).
- Promote patient engagement in research as an underpinning principle to all research in HVD.
- Some specific study ideas:
 - Develop a comprehensive public health study looking at valvular disease diagnosis and surveillance with special attention to the underserved. (PHAC/link with Aging initiatives).
 - Clinical and cost effectiveness research should be done consistently on all treatment and diagnostic options.
 - Horizon scanning of emerging technology options and their impact. (avoiding duplication across Canadian HTA agencies).
 - Benchmarking is needed between countries and provinces on patient characteristics and relation to procedure rates and outcomes.
 - Benefits and appropriateness of cardiac rehab programs and their adaptability to older frail adults.
 - Sex and gender research and other inequities/analysis in terms of research conducted and system access.



Issue

Goal

Systemic Policy Issues

Recommendations

Appendix A – Approach to Policy Roundtable and Participants

The Forum was an invitation-only event hosted by the Institute of Health Economics with support provided by Edwards Lifesciences, Boston Scientific, Abbott and Medtronic

Approach: The workshop report was conducted virtually and under Chatham House rule (i.e. non attribution of feedback). This was not intended to be a formal consensus but would involve iterative reflection from the group on the content.

Session one: Nov 19th (4 hours)

Major Objective:

• To receive feedback on the framing of issues and populating those with greater specificity in terms of recommendations.

Agenda: (meeting will be continuous - participants can take individual breaks as required)

- Introductions Overview of Initiative
- Presentation by IHE on Draft Backgrounder Report (Process and Key Findings)
- Review of Meeting logistics/format
- Conducting of breakout groups (3 groups) Brainstorming

(break)

• Return to Plenary - Quick Report back from Groups

Intervening week – Feedback from Session one was synthesized by the Institute of Health Economics. A revised report around themes, objectives and actions was prepared.

Session Two: Nov 26th (2 hours)

Major Objective:

To review and validate with synthesized feedback and suggestions/adaptation to recommendations section.

Agenda

Introductions Presentation of revised recommendations noting additions, or regroupings Review of key recommendations Feedback will be received verbally and via chat function

Post-event the final report was reviewed by the Steering Committee and some reordering and edits to the content were suggested and incorporated.



List of participants in the project:

Ms.	Shauna	Almas	Director of Development	Canadian Cardiovascular Society
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Ms.	Tamara	Blair	National Business Development Manager	Boston Scientific
Mr.	Ken	Bond	Director of Evidence Synthesis	Institute of Health Economics
Dr.	Eric	Cohen	Interventional Cardiologist, Deputy Head, Division of Cardiology	Sunnybrook Health Sciences Centre
Dr.	Neil	Fam	Director of Interventional Cardiology and Cardiac Cath Labs	Unity Health (St. Michael's Hospital)
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Dr.	Blair	O'Neill	Board Vice Chair; Associate Chief Medical Officer - Strategic Clinical Networks	Healthcare Excellence Canada; Alberta Health Services
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Ms.	Ellen	Ross	Managing Director	Heart Valve Voice Canada
Mr.	John	Sproule	Senior Policy Director	Institute of Health Economics
Mr.	Steven	St. George	Associate Director, Reimbursement and Health Care Economics	Abbott
Dr.	Rima	Styra	Director, Consultation Psychiatry	University of Toronto
Dr.	Ben	Tyrrell	Director of Cardiac Catherization Lab ; Director of the Transcatheter Aortic Valve Implantation Program	The CK Hui Heart Centre; The Mazankowski Heart Institute
Dr.	Robert	Welsh	Director, Adult Cardiac Catheterization and Interventional Cardiology Program; Vice President	Mazankowski Alberta Heart Institute; Canadian Association of Interventional Cardiology
Dr.	Harindra	Wijeysundera	Chief of the Schulich Heart Program	Sunnybrook Health Sciences Centre
Dr.	David	Wood	President; Interventional Cardiologist	Canadian Association of Interventional Cardiology; St. Paul's and Vancouver General Hospital
Mr.	Graham	Woodward	Former Senior Vice- President	CorHealth Ontario
Ms.	Nancy	Zuck	Consultant	Institute of Health Economics



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