

Memorandum

SUBJECT: CorHealth COVID-19 Cardiac Memo #4 – **RECOMMENDATIONS FOR AN ONTARIO APPROACH TO MANAGING CATHETER BASED STRUCTURAL HEART PROCEDURES DURING COVID-19**

TO: Cardiac Stakeholders
FROM: Office of the CEO, CorHealth Ontario
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DISCLAIMER: The information in this document represents general guidance based on current practice and available evidence. The document was developed by provincial clinical experts, reflecting best knowledge at the time of writing, and is subject to revision based on changing circumstances and conditions. This information is *intended to be "guidance rather than directive,"* and is *not meant to replace clinical judgment.* Reference to IPAC or Personal Protective Equipment (PPE) in this document should not replace or supersede the IPSC and PPE protocols or directives in place at your hospital.

Recommendations for an Ontario Approach to Managing Catheter Based Structural Heart Procedures during COVID-19

PREAMBLE

COVID-19 is an unprecedented crisis and poses a significant risk to the community as the landscape is rapidly evolving. The Ministry of Health has requested that all hospitals ramp down non-essential services, elective surgeries and other non-emergent clinical activity. CorHealth Ontario has been engaging with cardiac experts and stakeholders across the province to discuss how best to preserve health care capacity, in light of increasing COVID-19 cases requiring health care. The following guidance and recommendations reflect advice from this engagement.

GUIDING PRINCIPLES

1. Keeping front line health care providers healthy and patients protected is vital.
2. Minimizing the impact of COVID-19 on the mortality and morbidity of patients with cardiac disease is a priority.
3. Aligning with province- and hospital-specific infection prevention and control policies and protocols is important.
4. Promoting clinical activities aimed at preserving hospital resources (i.e. health care human resources, personal protective equipment, procedure rooms, Intensive Care Units, Emergency Departments) is a priority.

RECOMMENDATIONS

CorHealth Ontario, in consultation with key stakeholders, is making recommendations for the management of patients eligible for catheter-based structural heart procedures during the COVID-19 pandemic. These recommendations were created with the intention to limit as much as possible unintended harm to patients who are at high risk of mortality, if their conditions are left untreated. Patients requiring TAVI and Mitral Valve Clip are at high risk of mortality, morbidity and/or hospitalization if they contract COVID-19; as such, determination to treat these patients requires careful consideration of the risk of untreated structural heart conditions against the potential risk of exposure to COVID-19 in the hospital. This document is organized in 3 parts. Part 1 relates to the TAVI population, Part 2 to the mitral valve clip population, and Part 3 to other structural and congenital procedures.

PART 1: TAVI

1. CLINICAL STATUS

- 1.1 Access to TAVI in the context of the COVID-19 pandemic should only be considered for persons with symptomatic severe aortic stenosis (AS) based on the Interdisciplinary Heart Team (IHT) assessment of the following clinical characteristics:
 - High risk for repeated hospitalization for CHF/multiple syncopal episodes
 - Evidence for declining LV function
 - Evidence for declining renal function related to untreated AS
 - Failing bioprosthetic surgical valve
 - Critical AS Gradient >60 mm Hg
- 1.2 During COVID-19, regions or hospitals declaring a Level 2 or 3 COVID response (as per the Canadian Association of Interventional Cardiologists), should consider only performing TAVI on the inpatient population to facilitate hospital discharge.

2. INVESTIGATION

- 2.1 New referrals should be screened by the TAVI Team. Priority for further assessment should be given to Clinical Status scenarios, as highlighted in Recommendation 1.1.
- 2.2 Timely communication should be provided back to the referral MD as to assessment status (accepted or deferred assessment) with accompanying rationale.
- 2.3 The determination of patient acceptance for the procedure during the COVID-19 pandemic will be made by the hospital's designated Interdisciplinary Heart Team (IHT), and generally reserved for the purposes of preventing impending hospitalization or facilitating discharge.
- 2.4 Whenever possible, initial consultation should be by virtual contact (phone call +/- OTN hub), guiding and limiting need for onsite clinical visits, and available information should be utilized to consider rapid triage for further investigations for TAVR/SAVR or deferral for reassessment.
- 2.5 Duplication of echocardiogram (ECHO) study should be avoided if the referral source provides clear and compelling indications for pursuing TAVI work up, and study should be repeated only if ambiguity exists.
- 2.6 Imaging assessment for anatomic functional factors should continue to include computed tomography (CT).
- 2.7 Assessment for coronary disease with coronary angiography should be limited to patients who are at the highest risk defined as:
 - Angina CCS Class III or IV
 - High risk for underlying coronary artery disease; and/or
 - CT imaging that shows severe proximal multivessel coronary artery disease.
- 2.8 For patients with symptomatic low flow, low gradient aortic stenosis, the use of Dobutamine Stress Echo should currently be deferred. For those centres with existing expertise, the use of calcium scoring on the valve obtained by baseline CT should be considered as a surrogate marker of valve severity.

3. WAITLIST MANAGEMENT

- 3.1 Hospitals should ensure there is a process in place which includes assigned accountability for the active management of the aortic valve implantation waitlist(s). Mechanisms include ongoing review

of patient priority, as well as the assessment of the centres' ability to provide TAVI procedures during the COVID-19 pandemic.

- 3.2 All inpatients that meet the criteria, should be considered and prioritized first, regardless of their current hospital placement (i.e. whether they are at a structural heart centre or not).

4. CLINICAL PATHWAY

- 4.1 Where possible, centres will leverage clinical pathways (i.e. 3M - Vancouver Multidisciplinary, Multimodality, But Minimalist Clinical Pathway) to preserve health care resources and capacity. Pathways should consider:

- Avoidance of prolonged use of ICU resources (including intubation, ventilation);
- Need for PPE; and
- Prioritization for permanent pacemaker by day 2 post-TAVI.

- 4.2 Post-deployment screening ECHO should be done in a manner that is efficient and limits unnecessary movement within the hospital, and is in alignment with the CorHealth *Recommendations for an Ontario Approach to Provision of Hospital Echocardiography Services during COVID-19* (e.g. post valve deployment ECHO in the angio suite).

5. FOLLOW-UP

- 5.1 Centres should explore opportunity for remote follow-up utilizing technologies such as OTN.
- 5.2 In order to reduce the need to enter hospitals, follow up ECHO (at 1 month, 6 months, and one year) should be deferred during COVID-19 unless there is a change in symptoms.

PART 2: MITRAL VALVE CLIP

6. CLINICAL STATUS

- 6.1 Access to Mitral Valve Clip in the context of the COVID-19 pandemic should only be considered for persons with severe mitral regurgitation (> 2+ MR) and based on the Interdisciplinary Heart Team (IHT) assessment of the following clinical characteristics:
 - Inpatients with congestive heart failure with inability to discharge despite guideline-directed medical therapy;
 - Outpatients with persistent NYHA class III or IV symptoms despite guideline-directed medical therapy;
 - Outpatients with high risk of recurrent admissions for heart failure.

7. INVESTIGATION

- 7.1 Mitral valve clip requires both intubation/ventilation and TEE, which poses a risk to staff when treating patients who are COVID-positive or probable. The determination of patient acceptance for the procedure during the COVID-19 pandemic will be made by the hospital's designated Interdisciplinary Heart Team (IHT), and generally reserved for the purposes of preventing impending hospitalization or facilitating discharge.
- 7.2 Transesophageal echo screening, to assess anatomical suitability for a Mitral Valve Clip, should be:
 - restricted to patients meeting the above criteria (in 6.1) as assessed by the IHT;
 - performed by cardiologists with experience in assessment of anatomic suitability for mitral valve clipping (Level 3 training), to avoid the need for repeating TEEs.

- 7.3 Pre-mitral clip assessment for coronary artery disease with coronary angiography should be limited to patients for whom the decision to proceed with mitral clip will be affected by knowledge of the coronary anatomy; otherwise coronary angiography can be performed during the mitral clip procedure.

8. WAITLIST MANAGEMENT

- 8.1 Hospitals should ensure there is a process in place, which includes assigned accountability, for the *active* management of the mitral valve implantation waitlist(s). Mechanisms include ongoing review of patient priority as well as the assessment of the centres' ability related to resources/capacity during the COVID-19 pandemic.
- 8.2 Wait list management should consider and prioritize all inpatients that meet the criteria in section 6.1, regardless of their current hospital placement (i.e. whether they are at a structural heart centre or not).

9. CLINICAL PATHWAY

- 9.1 Centres will consider opportunities to preserve health care resources and capacity, including ICU diversion, where possible (e.g. extubation in the procedure room and admission to a step-down unit).
- 9.2 Post-deployment ECHO should be done in a manner that is efficient and limits unnecessary movement within the hospital, and in alignment with the *CorHealth Recommendations for an Ontario Approach to Provision of Hospital Echocardiography Services during COVID-19* (e.g. routine post procedure trans-thoracic echo before discharge is not necessary in all patients).

10. FOLLOW-UP

- 10.1 Centres should explore opportunity for remote follow-up utilizing technologies such as OTN.
- 10.2 Patients with severe LV dysfunction undergoing mitral clip for functional MR will continue to need heart function clinic follow-up post-procedure.
- 10.3 In order to reduce the need to enter hospitals, follow up ECHO (at 1 month, 6 months, and one year) should be deferred during COVID-19 unless there is a change in symptoms.

PART 3: OTHER STRUCTURAL/CONGENITAL PROCEDURES

11. OTHER PROCEDURES INCLUDING LAAC, PFO CLOSURE, ASD, COMPLEX CONGENITAL

- 11.1 Other routine structural heart procedures will be deferred unless there is an urgent/emergent need identified and discussed with the structural heart group at each center.
- 11.2 During COVID-19, LAAC or PFO closure for stroke prophylaxis should be considered for deferral to a later date.
- 11.3 Principles outlined for TAVI and Mitral Valve clip in terms of clinical status, investigations, waitlist management, procedural aspects (especially for intubation and TEE) and follow-up should be adhered to for other structural/congenital procedures to ensure they are appropriately done.