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GUIDES AND STANDARDS

Quality Standards for Transcatheter Aortic Valve Implantation (TAVI) in Québec

Produced by the Institut national d'excellence en santé et en services sociaux (INESSS)

Québec

Quality Standards for Transcatheter Aortic Valve Implantation (TAVI) in Québec

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Declaration of interests

The following individuals declare that they or their family members, their close friends, their close collaborators or organizations to which they are affiliated have interests, roles or professional activities that are, appear to be or could be in conflict with the assigned mandate with regard to the drug, technology or mode of intervention concerned by INESSS's work, including any alternative solution thereto.

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Responsibility

The Institut assumes entire responsibility for the final form and content of this document. The conclusions and recommendations do not necessarily reflect the opinion of the external reviewers or other individuals consulted for the purposes of this work.

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ACRONYMS AND ABBREVIATIONS

AATS	American Association for Thoracic Surgery
ACC	American College of Cardiology
ACCF	American College of Cardiology Foundation
AHA	American Heart Association
ANZSCTS	Australian and New Zealand Society of Cardiac and Thoracic Surgeons
AV	atrioventricular
AVR	aortic valve replacement
BMI	body mass index
CCN	Cardiac Care Network of Ontario
CCS	Canadian Cardiovascular Society
CEU	Cardiovascular Evaluation Unit
CFPC	College of Family Physicians of Canada
CSANZ	Cardiac Society of Australia and New Zealand
D_{LCO}	diffusing capacity of the lungs for carbon monoxide
EACTS	European Association for Cardio-Thoracic Surgery
eGFR	estimated glomerular filtration rate
ESC	European Society of Cardiology
FEV_1	forced expiratory volume per second
FRANCE 2	French Aortic National CoreValve and Edwards 2
GARY	German Aortic Valve Registry
HAS	Haute Autorité de Santé (France)
Hb	hemoglobin
HTA	health technology assessment
INESSS	Institut national d'excellence en santé et en services sociaux (Québec)
MMSE	Mini-Mental State Examination
MSCT	multislice computed tomography
MSSS	Ministère de la Santé et des Services sociaux (Québec)
NYHA	New York Heart Association
ÖGTHC	Austrian Society of Thoracic and Cardiovascular Surgery
ÖKG	Austrian Society of Cardiology
RQCT	Réseau québécois de cardiologie tertiaire
SAVR	surgical aortic valve replacement
SCAI	Society for Cardiovascular Angiography and Interventions

STS	Society of Thoracic Surgeons
STS PROM	Society of Thoracic Surgeons Predicted Risk of Mortality
TAVI	transcatheter aortic valve implantation
TEE	transesophageal echocardiography
TTE	transthoracic echocardiography
TVT	transcatheter valve therapy
VARC-2	Valve Academic Research Consortium-2

BACKGROUND

Treatment for severe chronic aortic valve stenosis

Aortic valve stenosis occurs when the opening of the aortic valve narrows. This narrowing reduces or blocks blood flow from the heart's left ventricle into the aorta. Patients with aortic stenosis can remain asymptomatic for a long time. However, once they start having symptoms (shortness of breath, angina, fainting), their condition can deteriorate quickly and the risk of mortality increases. For many years, the only effective treatment for severe aortic stenosis was surgery to replace the valve with a mechanical or biological prosthesis. This invasive procedure requires placing the patient under general anaesthesia and opening the sternum, and can be difficult or impossible to tolerate especially for older patients or those with comorbidities. In such cases, such a procedure might be considered too risky to be an option. In 2002, a new technique was developed that made it possible to implant another type of bioprosthesis using catheterization (transcatheter aortic valve implantation [TAVI]). This procedure is less invasive because it facilitates access to the heart without requiring surgical opening of the sternum and, moreover, involves shorter recovery times and length of stay in hospital. Although the clinical outcomes of TAVI are increasingly documented, they are still less well-known than those for conventional surgery, and as a result, some uncertainty remains.

Current knowledge in the literature and real-world evidence

In 2010, the Ministère de la Santé et des Services sociaux (MSSS) asked the Cardiovascular Evaluation Unit (CEU) of the Institut national d'excellence en santé et en services sociaux (INESSS) to conduct a systematic review of the evidence on TAVI. This review led to an information brief being published in May, 2012 [INESSS, 2012].[1] The MSSS also mandated the CEU to conduct a field evaluation in order to provide an overview of the use of TAVI in the 'real-world' practice setting in Québec. The report for the 2013-2015 period was published online in April, 2016 [INESSS, 2016].[2]

The literature review that led to the publication of the 2012 information brief highlighted variability in clinical outcomes (survival, adverse events) that pointed to an overall lack of certainty regarding risks and net benefits, especially in the long term.

Because of this lack of certainty, it was recommended in the information brief that TAVI be considered only for patients for whom cardiac valve replacement surgery is deemed too high risk, among other statements [INESSS, 2012]. The results of the real-world evaluation showed that, in Québec, the use of TAVI is in line with the recommendations issued in 2012. Most patients selected for TAVI between 2013 and 2015 in the province were older (> 80 years of age) and had significant comorbidities, and therefore presented a high surgical risk.

[1] Available at: https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Cardio/ETMIS2012_Vol8_No8.pdf

[2] Available at: https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Cardio/INESSS_TAVI_2016.pdf

The 2012 information brief also recommended that the decision to use TAVI be made collaboratively by a multidisciplinary team, such that the procedure is performed only for patients with sufficient anticipated benefits, notably a significant improvement in their quality of life that is maintained for at least one year.

Today, six institutions in Québec have implemented a TAVI program [MSSS, 2015]. The number of procedures performed each year is increasing significantly, and so is the body of evidence supporting this practice, particularly with regard to patient selection. It was therefore necessary to produce an update on current knowledge, which was published online by INESSS on April 21, 2016. This update highlights the fact that the indication for TAVI, which used to be limited to patients at high surgical risk, has been expanded to include patients at lower risk. Guidelines published by the American Heart Association (AHA) in 2017 recognize that this mode of intervention is reasonable for patients that are considered intermediate risk (see Table 1). This recommendation is supported by two randomized trials that concluded that TAVI is a "noninferior alternative" to surgical valve replacement [Reardon et al., 2017; Leon et al., 2016]. However, additional evidence is required regarding the long-term outcomes of TAVI compared to surgery in younger, lower-risk patients, particularly with regard to the durability of implants or the need for subsequent intervention. Clinical trials have recently started, and data should be available shortly to determine whether using this procedure provides added value for this category of patients.

Table 1 Preferred options for valve replacement in patients with severe symptomatic aortic valve stenosis [Nishimura et al., 2017]

Surgical risk	Low	Intermediate	High	Prohibitive (inoperable patients)
Preferred option	Conventional surgical replacement	Conventional surgical replacement OR TAVI	Conventional surgical replacement OR TAVI	TAVI

As for costs,[3] TAVI (approximately $44,000 CAN) is more expensive than surgery (approximately $23,000 CAN). The difference is mainly due to the higher price of TAVI implants compared to surgical ones, because of the different and innovative nature of the former type. The cost-effectiveness of TAVI for patients at intermediate risk has not yet been clearly established.

Selecting patients for TAVI: A complex process

Keeping in mind that each patient is unique, it should be specified that TAVI is considered in cases where it is likely to provide benefits over surgery, such as for patients at prohibitive surgical risk or with anatomical particularities. For patients at intermediate or high surgical risk, selecting one option over another is complex, and it is the role of the multidisciplinary TAVI

[3] Average costs of $22,984 per episode of care for conventional surgery vs. $44,374 for TAVI have been reported in Québec [Gleeton et al., 2015]. Average costs of $29,163 per episode of care for conventional surgery vs. $49,796 for TAVI have been reported in Ontario [Wijeysundera et al., 2016].

team to weigh all the information pertaining to each patient's situation to determine the surgical risk. The level of risk is based on a global assessment which integrates the patient's surgical risk score (STS PROM or EuroSCORE), evaluation of the degree of frailty and assessment of pathologies affecting the major organs as well as the specific risks of the procedure, in order to ultimately determine which option to favour. Conventional surgical replacement remains the preferred option for low-risk patients.

Quality standards for optimal, standardized use of TAVI in Québec

The MSSS mandated INESSS to establish quality standards in collaboration with the Réseau québécois de cardiologie tertiaire (RQCT) and the designated TAVI institutions. As a result of this collaborative work, the present guide proposes 29 quality standards for the practice of TAVI. These standards fall under three categories: 1) organizational aspects (structures and processes) of a TAVI program; 2) assessment, decision-making and judicious selection of patients; and 3) post-procedure patient management and follow-up.

INTRODUCTION

At the request of the Ministère de la Santé et des Services sociaux (MSSS), the Cardiovascular Evaluation Unit (CEU) of the Institut national d'excellence en santé et en services sociaux (INESSS) conducted a systematic review of the evidence on transcatheter aortic valve implantation (TAVI) and published an information brief on the topic in May, 2012 [INESSS, 2012]. Based on the brief's recommendations, TAVI is to be considered as a treatment option only for patients whose symptoms can be attributed to severe symptomatic aortic stenosis and who have contraindications to or are deemed too high risk for cardiac valve replacement surgery [INESSS, 2012]. In addition, the decision to perform a TAVI procedure should be the result of a multidisciplinary consultation process such that only patients with sufficient anticipated benefits are selected, in accordance with clinical practice guidelines.

The practice of TAVI and the evidence supporting its use are evolving very quickly, particularly with regard to patient selection. In 2016, American and European legislators recognized the use of TAVI devices in patients at intermediate risk,[4] and a recommendation for such use was issued in practice guidelines for the first time [Nishimura et al., 2017; Vandvik et al., 2016].

Objective

As we move toward using transcatheter aortic valve implantation in lower-risk patients, the MSSS has expanded INESSS's mandate, by requiring it to establish, in collaboration with the Réseau québécois de cardiologie tertiaire (RQCT) and the designated TAVI institutions, standards to promote and facilitate optimal and standardized use of TAVI in the centres offering such a program.

[4] On August 1, 2016, the CoreValve™ Evolut™ R device received Conformité Européenne approval, and on August 18, 2016, the SAPIEN XT and SAPIEN 3 devices were approved by the United States Food and Drug Administration.

METHODS

INESSS prepared the present document in collaboration with an advisory committee of experts in cardiac surgery, cardiology and nursing science from all the Québec institutions with a TAVI program. The committee members were selected jointly by the CEU and the RQCT.

The CEU developed the content of this guide by consensus with the clinical experts, based on a systematic review of the scientific literature. The review is published as a separate document presenting current knowledge on TAVI, and aims to answer the following questions:

- What are the current clinical practice guidelines or expert consensus statements for TAVI?
- What are the clinical outcomes of TAVI compared to those of conventional surgical aortic valve replacement (SAVR) in intermediate-risk patients?
- What patient characteristics can serve as factors to predict clinical outcomes of TAVI?
- How do the costs of TAVI compare to those of SAVR in intermediate-risk patients?
- What quality indicators apply to the practice of TAVI?

Preliminary statements were developed based on the retrieval and critical assessment of evidence from the sources of information consulted, particularly from practice guidelines, and were set out in a working document.

This working document was emailed to the advisory committee members, who commented on the clarity, accuracy and relevance of the statements during successive rounds of consultation. For transparency purposes, anonymized comments were shared along with proposed new wording during each round of emails sent to the committee members.

The members of the advisory committee and of the INESSS CEU met in person in March, 2017 to discuss and agree on the final wording of each statement.

The document was submitted for external scientific validation by a monitoring committee made up of the RQCT executive committee members and by external reviewers.

Lastly, revised statements were emailed to the advisory committee members for final approval.

Management of conflicts of interests

Measures have been taken to mitigate the potential impact of the conflicts of interests disclosed by the authors:

- The advisory committee membership allowed for representation of a variety of medical specialties and fields of practice relevant to the work. In addition to interventional cardiologists, members from the fields of non-interventional cardiology, cardiac surgery, geriatrics and clinical administration were consulted.
- The advisory committee included representatives from the six institutions with TAVI programs in Québec.
- Members' comments during the consultation rounds were anonymized before being shared.
- In line with the methodology used by Health Quality Ontario to develop quality standards [HQO, 2016], the recommendations taken from the various guidelines in the literature were extracted and compared, and were used as a basis to develop quality statements.
- Ultimately, none of the standards issued are based exclusively on the opinion of advisory committee members. Each standard is supported in whole or in part by at least one relevant external source document.

QUALITY STANDARDS

Following the review of the relevant evidence and the collaborative work done with the advisory committee members, 29 quality standards for the practice of transcatheter aortic valve implantation were developed and categorized as follows:

Table 2 Quality standards for transcatheter aortic valve implantation (TAVI) in Québec

1. Organizational standards for a transcatheter aortic valve implantation program (14 standards)	**2. Standards for assessment, decision-making and patient selection (11 standards)**	**3. Standards for post-procedure patient management and follow-up (4 standards)**
1.1 Structures and processes at institutions (7)	**2.1** Pre-procedure assessment (8)	**3.1** Post-procedure management and discharge (1)
1.2 Composition of the multidisciplinary TAVI team (3)	**2.2** Decision-making with the patient (1)	**3.2** Patient follow-up (3)
1.3 Training/qualifications (2)	**2.3** Patient selection (2)	
1.4 Wait times and waiting list (1)		
1.5 Data registry (1)		

Each standard has a three-digit identifier and is presented in a box. All excerpts from the source documents relevant to each of the statements are available in the report titled *Normes de qualité relatives à l'implantation valvulaire aortique par cathéter (TAVI) au Québec. Annexe*.

MAIN SOURCE DOCUMENTS

INESSS 2012: Implantation valvulaire aortique par cathéter : évaluation des données probantes et synthèse des considérations organisationnelles [INESSS, 2012]

CCS 2012: Transcatheter aortic valve implantation: A Canadian Cardiovascular Society position statement [Webb et al., 2012]

VARC-2 2012: Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document (VARC-2) [Kappetein et al., 2012]

AATS / ACCF / SCAI / STS 2012: Multisociety (AATS, ACCF, SCAI, and STS) expert consensus statement: Operator and institutional requirements for transcatheter valve repair and replacement, Part 1: Transcatheter aortic valve replacement [Tommaso et al., 2012]

ESC / EACTS 2012: Guidelines on the management of valvular heart disease (version 2012) [Vahanian et al., 2012]

ÖKG / ÖGTHC 2012: Terms of agreement between the Austrian Society of Cardiology and the Austrian Society of Thoracic and Cardiovascular Surgery on transcatheter heart valve interventions [Wisser et al., 2012]

German Aortic Valve Registry (GARY) 2013: German Aortic Valve Score: A new scoring system for prediction of mortality related to aortic valve procedures in adults [Kötting et al., 2013]

CCN 2014: Quality-Based Procedures Clinical Handbook for Aortic Valve Disease [CCN and MOHLTC, 2014]

AHA / ACC 2014: 2014 AHA/ACC guideline for the management of patients with valvular heart disease [Nishimura et al., 2014]

French Aortic National CoreValve and Edwards (FRANCE) 2 2014: Predictive factors of early mortality after transcatheter aortic valve implantation: Individual risk assessment using a simple score [Iung et al., 2014]

MSSS 2015: *Orientations ministérielles – Implantation valvulaire aortique par cathéter* [MSSS, 2015]

CSANZ / ANZSCTS 2015: Position statement for the operator and institutional requirements for a transcatheter aortic valve implantation (TAVI) program [Walters et al., 2015]

CCS QI 2016: Quality of care for transcatheter aortic valve implantation: Development of Canadian Cardiovascular Society quality indicators [Asgar et al., 2016]

HAS 2015: *Réévaluation des critères d'éligibilité des centres implantant des bioprothèses valvulaires aortiques par voie artérielle transcutanée ou par voie transapicale* [HAS, 2015]

Hinterbuchner 2016: Frailty scoring in transcatheter aortic valve replacement patients [Hinterbuchner et al., 2016]

Aranzulla 2016: Follow-up management after transcatheter aortic valve implantation (TAVI) [Aranzulla et al., 2016]

Lauck 2016: Vancouver transcatheter aortic valve replacement clinical pathway: Minimalist approach, standardized care, and discharge criteria to reduce length of stay [Lauck et al., 2016]

Puri 2016: TAVI or No TAVI: Identifying patients unlikely to benefit from transcatheter aortic valve implantation [Puri et al., 2016]

STS / ACC TVT 2016: Development and validation of a risk prediction model for in-hospital mortality after transcatheter aortic valve replacement [Edwards et al., 2016]

ACC 2017: 2017 ACC expert consensus decision pathway for transcatheter aortic valve replacement in the management of adults with aortic stenosis [Otto et al., 2017]

AHA 2017: 2017 AHA/ACC focused update of the 2014 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 Clinical Practice Guidelines [Nishimura et al., 2017]

1 ORGANIZATIONAL STANDARDS FOR A TRANSCATHETER AORTIC VALVE IMPLANTATION PROGRAM

TAVI practice guidelines often mention organizational elements required for a transcatheter aortic valve implantation program to run smoothly. The topics addressed by the standards in this section include:

- the structures and processes at the health care centres or institutions that have a TAVI program;
- the composition of the multidisciplinary TAVI team that is responsible for evaluating each potential candidate for the procedure;
- operator training/qualifications;
- wait times and waiting list management.

1.1 Structures and processes at institutions

In Québec, the activities of a set number of TAVI programs are initiated and maintained in an organized fashion in order to:

- concentrate and maintain expertise;
- set and maintain uniform patient selection criteria and standardized reporting variables and methods;
- ensure follow-up of procedures and management of the quality of care at each centre.

1.1.1 Each centre that performs aortic valve implantations must be specifically designated by the MSSS, whose prior approval is required for a new program to be initiated.

Sources: MSSS 2015, HAS 2015

A TAVI program should be considered only by institutions with well-established cardiac surgery and interventional cardiology programs, a high volume of activity and a wide selection of treatment options.

1.1.2 TAVI procedures should be performed only in centres that have:

- **cardiac surgery programs with an annual volume of at least 75 SAVRs;**
- **a multidisciplinary team formed in accordance with the composition set out in standards 1.2.1 and 1.2.2.**

Sources: AATS / ACCF / SCAI / STS 2012, CCS 2012, ESC / EACTS 2012, AHA / ACC 2014, CSANZ / ANZSCTS 2015, expert consensus

1.1.3 TAVI procedures should be performed only in centres that have:

- **an interventional cardiology program with a volume of activity of at least 1000 cardiac catheterizations and 400 percutaneous coronary interventions;**
- **a multidisciplinary team formed in accordance with the composition set out in standards 1.2.1 and 1.2.2.**

Sources: AATS / ACCF / SCAI / STS 2012, CSANZ / ANZSCTS 2015, expert consensus

TAVIs are performed in highly-specialized centres that have advanced equipment. The purpose of the following statements is to list the minimum resources necessary to run a TAVI program.

1.1.4 For each program involving TAVI, the following components should be accessible directly (that is, without requiring interhospital transfer):

- **an operating room or hybrid room of sufficient size to be able to use the equipment required for implantations, including space for anaesthesia, echocardiography and extracorporeal membrane oxygenation and necessary medical and paramedical staff;**
- **the appropriate equipment to perform the procedure and treat potential complications such as a complete atrioventricular (AV) block, rupture of a major vessel, cardiac tamponade and cardiogenic shock, or any other cardiovascular or pulmonary complication;**
- **a post-procedure intensive care room with staff experienced in the management of patients with complex cardiac conditions, including those that have had conventional cardiac surgery.**

1.1.5 For each program involving TAVI, the following services should be accessible directly:

- **transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE);**
- **multislice computed tomography (MSCT);**
- **extracorporeal life support;**
- **a perfusionist team;**
- **renal replacement therapy;**
- **vascular surgery and percutaneous vascular procedures.**

Sources: INESSS 2012, CCS 2012, AATS / ACCF / SCAI / STS 2012, ÖKG / ÖGTHC 2012, HAS 2015, CSANZ / ANZSCTS 2015, ACC 2017, expert consensus

Human and financial resources must also be allocated for the many activities associated with the program, including patient selection and follow-up, to ensure program stability and sustainability.

1.1.6 A TAVI program must receive administrative, financial, professional and logistical support, not only with regard to selecting patients, obtaining consent and performing the procedure, but also in order to permit patient follow-up, documentation of information in charts, management of the waiting list and maintenance of a local registry of relevant program data.

Sources: AATS / ACCF / SCAI / STS 2012, INESSS 2012, expert consensus

In the case of complications arising during a TAVI procedure, an emergency response plan should be made in agreement with the patient and include the human and material resources needed for its execution.

1.1.7 An interventional cardiologist and a cardiac surgeon should be available on site during a TAVI in order to appropriately respond to any possible complications during the procedure.

Sources: INESSS 2012, ÖKG / ÖGTHC 2012, HAS 2015, ACC 2017, expert consensus

1.2 Composition of the multidisciplinary TAVI team

The scientific literature supports the notion that formal multidisciplinary collaboration between professionals is fundamental to optimizing the patient selection process, as it encourages a deeper understanding of risk-benefit ratios. Furthermore, the scope of the multidisciplinary TAVI team's work encompasses all aspects of the transcatheter aortic valve implantation program, including patient follow-up after the procedure.

1.2.1 The multidisciplinary TAVI team must include at least one interventional cardiologist and one cardiac surgeon, to whom an imaging expert and a program coordinator should be added.

Sources: INESSS 2012, CCS 2012, ESC / EACTS 2012, AATS / ACCF / SCAI / STS 2012, VARC-2 2012, CCN 2014, AHA / ACC 2014, CCS QI 2016, CSANZ / ANZSCTS 2015, MSSS 2015, HAS 2015, ACC 2017

1.2.2 The multidisciplinary TAVI team should have access to complementary medical and paramedical expertise when deemed relevant (e.g., an anaesthesiologist, a geriatrician internist and any other medical staff, as needed).

Sources: INESSS 2012, AATS / ACCF / SCAI / STS 2012, AHA / ACC 2014, CSANZ / ANZSCTS 2015, MSSS 2015, HAS 2015, expert consensus

1.2.3 The multidisciplinary team members should meet regularly to work together on all aspects of the TAVI program, that is, the development of an individualized treatment plan for each patient that takes into account all options for treatment, evaluation of eligibility, the procedure itself, post-procedure care and long-term follow-up.

The decisions made at these meetings must be recorded to ensure the traceability of information.

Sources: INESSS 2012, AATS / ACCF / SCAI / STS 2012, VARC-2 2012, CSANZ / ANZSCTS 2015, MSSS 2015, HAS 2015, ACC 2017, expert consensus

1.3 Training/qualifications

A TAVI is without a doubt a complex procedure, which requires operators to be well-trained in order to master all of its aspects. Furthermore, the scientific literature indicates a relationship between the volume of procedures performed and favourable outcomes. It should therefore be a requirement that the program as a whole, but also the operators themselves, meet a certain threshold in terms of annual volume of transcatheter aortic valve implantation activity.

1.3.1 In order to perform the intervention as the primary operator, cardiac surgeons and interventional cardiologists should have received specific training on the device being used and been supervised by an expert and deemed fit to proceed independently (proctored).

Sources: INESSS 2012, CCS 2012, AATS / ACCF / SCAI / STS 2012, CSANZ / ANZSCTS 2015, expert consensus

1.3.2 In order to maintain the level of expertise required by the care teams:

- **at least 30 TAVI procedures per year should be performed as part of the TAVI program;**
- **all clinicians should perform at least 20 procedures per year as either a primary or secondary operator.**

Sources:
CCS 2012 (25–50 procedures per program),
AATS / ACCF / SCAI / STS 2012 (24 procedures per program),
CSANZ / ANZSCTS 2015 (20 procedures per program),
MSSS 2015 (30 procedures per program),
HAS 2015 (24 procedures per program),
expert consensus

1.4 Wait times and waiting list

TAVI wait times reflect the ability of centres to perform timely evaluations and provide access to the procedure within an appropriate delay.

1.4.1 For consistency, a TAVI program should use the Canadian Cardiovascular Society's definitions when recording data about wait times:

- **the evaluation time for the patient who will potentially undergo the procedure, starting from the time the multidisciplinary TAVI team is assigned the file;**
- **the procedural wait time, starting from the time the multidisciplinary TAVI team makes its recommendation to go forward with the procedure.**

The program should also document the order of priority of patients on the waiting list.

If a patient is consulting in order to obtain a second opinion, communication should be established with the centre that provided the first opinion.

Sources: CCN 2014, CCS QI 2016, expert consensus

1.5 Data registry

The guidance document (*orientations ministérielles*) published by the MSSS in 2015 recommends that each centre that performs transcatheter aortic valve implantations maintain a local registry that can be used to assess the short-, medium- and long-term effects of the use of these devices on the health status and quality of life of patients [MSSS, 2015]. It is advisable that an interdisciplinary continuous improvement committee hold regular meetings to specifically follow-up on TAVI cases in terms of clinical outcomes, complications, morbidity and mortality, as well as on all cases of aortic stenosis that are not approved for TAVI and instead referred to standard surgical treatment. This committee should keep a record of the meetings and make a list of possible improvements. Ideally, it should submit a continuous improvement plan to the institution's Council of Physicians, Dentists and Pharmacists.

1.5.1 Each centre that performs TAVI procedures should maintain a local database of the parameters relevant to its program, according to the quality standards and indicators to be established for Québec. This database should contain information on all patients assessed by the multidisciplinary TAVI team, whether the treatment option chosen was AVR, transcatheter aortic valve implantation or medical treatment. Each centre should also perform an annual review to follow-up on its clinical outcomes.

Sources: INESSS 2012, AATS / ACCF / SCAI / STS 2012, ÖKG / ÖGTHC 2012, CCN 2014, CCS QI 2016, MSSS 2015, ACC 2017, expert consensus

2 STANDARDS FOR ASSESSMENT, DECISION-MAKING AND PATIENT SELECTION

Pre-procedure assessment of potential candidates for transcatheter aortic valve implantation provides the multidisciplinary TAVI team with the material needed in order to decide on the best treatment option with each patient. This process also involves the notions of life expectancy and quality of life.

Documentation of the surgical risk (low, intermediate, high, prohibitive) is an essential step at this stage. However, there is still no tool specific to patients being assessed for TAVI that looks at all the relevant parameters and quantifies each one's level of influence to yield a precise risk score. As a result, it is up to the multidisciplinary TAVI team to perform this exercise and weigh all information specific to a given patient, including the elements listed in the present section.

2.1 Pre-procedure assessment

2.1.1 The pre-procedure assessment should be documented in the chart and include, at a minimum:

- **the symptoms and severity of the aortic stenosis;**
- **an assessment of the anatomical criteria necessary to determine the size of the aortic annulus, the appropriate implant and the preferred approach;**
- **an assessment of the anatomical criteria that contraindicate the surgical approach, such as porcelain aorta, bypass adherent to the sternum and/or hostile thorax;**
- **a review of any previous procedures;**
- **other relevant comorbidities.**

Sources: CCS 2012, CCN 2014, AHA / ACC 2014, ACC 2017, expert consensus

2.1.2 The pre-procedure assessment documented in the chart should include an evaluation of global cardiac function, paying particular attention to the following cardiovascular factors associated with unfavourable outcomes:

- **New York Heart Association (NYHA) functional class IV;**
- **indicators of left ventricular dysfunction:**
  - **left ventricular ejection fraction;**
  - **stroke volume index;**
- **severe pulmonary arterial hypertension;**
- **atrial fibrillation or other relevant arrhythmia;**
- **associated heart valve disease;**
- **peripheral vascular disease.**

Sources: Puri 2016, ACC 2017, expert consensus

2.1.3 The pre-procedure assessment documented in the chart should pay particular attention to the following non-cardiovascular factors associated with unfavourable outcomes:

- **active neoplasia with limited life expectancy;**
- **severe chronic kidney disease (estimated glomerular filtration rate [eGFR]: < 30 ml/min or on dialysis);**
- **severe pulmonary disease (oxygen dependence, forced expiratory volume per second [FEV_1]: < 50% predicted, or diffusing capacity of the lungs for carbon monoxide [D_{LCO}] : < 50% predicted);**
- **severe diabetes with multiple complications;**
- **degenerative neurological disorder that significantly limits mobility or life expectancy;**
- **inflammatory bowel disease;**
- **cirrhosis, esophageal varices, active gastrointestinal bleeding with limited ability to take antiplatelet and anticoagulant agents;**
- **involuntary weight loss;**
- **body mass index (BMI) < 18.5.**

Sources: Puri 2016, ACC 2017, expert consensus

2.1.4 The pre-procedure assessment documented in the chart should include:

- **evaluation of surgical risk using the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) scale;**
- **assignment of functional classification according to the New York Heart Association (NYHA) scale.**

Sources: ESC / EACTS 2012, AHA / ACC 2014, CCS QI 2016, ACC 2017

The aspects closely related to what is called the patient's "degree of frailty"—that is, cognitive functioning and functional level—are also relevant to the multidisciplinary TAVI team's considerations.

2.1.5 The cognitive function assessment should be documented in the chart.

If there is any sign of possible impairment, the assessment should be performed by administering one or more validated tests.

Sources: INESSS 2012, CCS 2012, ESC / EACTS 2012, VARC-2 2012, Puri 2016, ACC 2017, expert consensus

If patients do not demonstrate full cognitive functioning, use of Folstein's Mini-Mental State Examination (MMSE) is suggested to identify patients that have dementia (score < 24) [Otto et al., 2017].

Since depression can hinder cognitive performance, it may be relevant to also use a tool such as Yesavage's Geriatric Depression Scale [Otto et al., 2017].

2.1.6 The functional assessment should be documented in the chart and include an evaluation of autonomy in the performance of basic activities of daily living (self-feeding, hygiene, toileting, bathing, mobility, and dressing).

If there is any sign of possible impairment, the assessment should be performed by administering one or more validated tests.

Sources: INESSS 2012, AHA / ACC 2014, ACC 2017, expert consensus

If patients do not demonstrate full functionality, a tool such as the Katz Index of Independence in Activities of Daily Living may help determine the nature of the limitations [Hinterbuchner et al., 2016; Puri et al., 2016].

2.1.7 The degree-of-frailty assessment should be documented in the chart.

If there is any sign of frailty, the assessment should be performed by administering one or more validated tests.

If the patient appears to be fragile, he/she should be assessed by an internist or geriatrician.

Sources: INESSS 2012, AHA / ACC 2014, Hinterbuchner 2016, Puri 2016, ACC 2017, expert consensus

If patients show signs of possible frailty, further testing could involve the following validated tools:

- the Essential Frailty Toolset [Afilalo et al., 2017]
  - weakness assessment (**1 point** if the time needed to rise from a chair five times without using one's hand > 15 seconds, **2 points** if the person is unable to complete the test);
  - cognitive impairment (**1 point** if the Mini-Cog Test is positive or MMSE score < 24)
  - anemia (**1 point** if hemoglobin < 130 g/L for men or < 120 g/L for women)
  - hypoalbuminemia (**1 point** if albumin < 35 g/L)

  (Total score: 0 = nonfrail, 1–2 = pre-frail stage, 3–5 = frail);
- 5-metre walk test;
- Rockwood's Clinical Frailty Scale.

The very concept of a multidisciplinary TAVI team is that it should be responsive and offer each patient expertise from different fields, according to his or her particular conditions, in order to exercise the judgment required.

2.1.8 If the previously-assessed aspects, which include the patient's functional capacity, cognitive functioning and frailty, are such that the potential impact of a TAVI on quality of life is uncertain, a geriatric medical evaluation should be obtained.

Sources: INESSS 2012, Puri 2016, expert consensus

2.2 Decision-making with the patient

The decision to perform a TAVI must be the result of an open conversation between the parties involved.

2.2.1 The patient and his or her loved ones' goals and expectations should be established early in the process, in a transparent manner and with an appropriate level of language for discussing the following: care objectives, risks and consequences of a TAVI, anticipated improvement of symptoms and life expectancy, and other treatment options, including no intervention.

Sources: INESSS 2012, AHA / ACC 2014, CCN 2014, ACC 2017, expert consensus

2.3 Patient selection

Judicious selection of patients for TAVI is a complex process that requires thorough consideration. For a procedure to be deemed useful (as opposed to futile), it must offer a positive impact on life expectancy and quality of life. The best strategy for maximizing the utility of the procedure and minimizing its futility takes into account the patient's morbidity profile, the potential risks and anticipated benefits and the uncertain durability of the implants, in addition to economic considerations such as the burden placed on the health care system and the costs of the procedure [Abdelghani and Serruys, 2016].

Based on current knowledge, TAVI is recommended for patients at high surgical risk, conditional on an assessment of the procedural risks and each patient's personal values and preferences [Nishimura et al., 2017]. This approach is also well-founded from an economic standpoint, considering both its clinical benefits and the additional costs it incurs [Reynolds et al., 2016; Potter et al., 2015].

However, for patients at intermediate surgical risk, the evidence is less conclusive. In terms of clinical outcomes (death or disabling stroke at two years), large-scale randomized studies have shown transcatheter aortic valve implantation to be non-inferior to surgery [Reardon et al., 2017; Leon et al., 2016], making it a reasonable conditional alternative to surgery [Nishimura et al., 2017], but at higher cost. In reality, therefore, it is not the most cost-efficient approach for patients at intermediate surgical risk [Ailawadi et al., 2016].

In the context of limited resources, it is thus up to the multidisciplinary team to use its judgment when making recommendations and give priority to patients for whom TAVI remains the only treatment option.

2.3.1 It is advisable to avoid performing TAVI on patients who are not likely to see an improvement in their life expectancy and quality of life. This refers to patients for whom, even if the procedure is successful:

- **life expectancy is less than one year;**
- **it is anticipated that there is a low probability of improving quality of life and/or life expectancy.**

Sources: INESSS 2012, VARC-2 2012, AHA / ACC 2014, Puri 2016, ACC 2017

2.3.2 Based on all the information gathered, the multidisciplinary TAVI team should:

- **determine the risk-benefit ratio for each treatment option;**
- **document the surgical risk (low, intermediate, high, prohibitive);**
- **propose one of the following three treatment options:**
    - **surgical aortic valve replacement (AVR);**
    - **transcatheter aortic valve implantation;**
    - **medical treatment.**

Sources: INESSS 2012, VARC-2 2012, AHA / ACC 2014, CSANZ / ANZSCTS 2015, ACC 2017, expert consensus

3 STANDARDS FOR POST-PROCEDURE PATIENT MANAGEMENT AND FOLLOW-UP

3.1 Post-procedure management and discharge

Although TAVI procedures are performed in specialized centres, the care of each patient must eventually be assumed in the general community.

3.1.1 Each program should have a written protocol regarding post-procedure patient management, discharge and reintegration into the community.

Sources: CCN 2014, Lauck 2016, ACC 2017, expert consensus

3.2 Patient follow-up

3.2.1 Regardless of the follow-up performed by the attending physician, the multidisciplinary TAVI team should assume responsibility for patient follow-up for at least the first 30 days following the procedure. At the end of this period, a formal transfer should be made to the attending physician, who will ensure subsequent follow-up. The attending physician should be provided with all the information relevant to the episode of care.

Sources: Aranzulla 2016, ACC 2017, expert consensus

3.2.2 The multidisciplinary TAVI team should, however, contact patients one year after their procedure to inquire about their situation and record this information, which will allow the interdisciplinary continuous improvement committee to track clinical outcomes specific to the program each year and make any necessary adjustments.

Sources: Aranzulla 2016, ACC 2017, expert consensus

3.2.3 A stable patient with no complications and few comorbidities should be evaluated within six months following the procedure by the referring physician, then once a year or more frequently as needed, if there are complications or concomitant medical conditions.

If the valve is suspected of functioning poorly, the patient should be referred back to the multidisciplinary TAVI team.

Sources: Aranzulla 2016, ACC 2017, expert consensus

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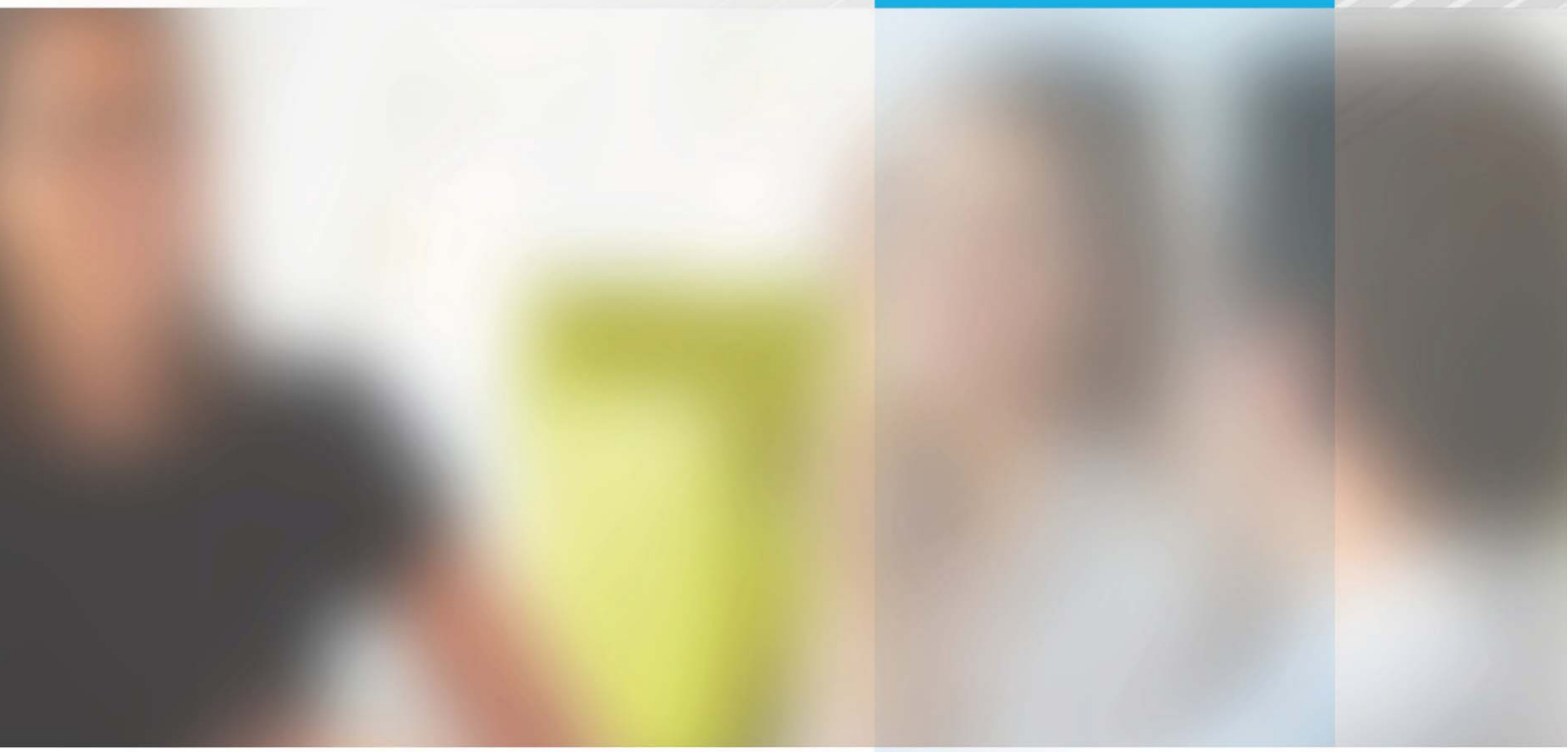

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