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GUIDES ET NORMES

Normes de qualité relatives à l'implantation valvulaire aortique par cathéter (TAVI) au Québec

Annexe

Québec

Normes de qualité relatives à l’implantation valvulaire aortique par cathéter (TAVI) au Québec

Annexe

Rédigé par
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Le présent document contient l'annexe complémentaire de l'état des connaissances sur l'implantation valvulaire aortique par cathéter (TAVI).

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Renseignements

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INESSS 2012: Implantation valvulaire aortique par cathéter : évaluation des données probantes et synthèse des considérations organisationnelles [Institut national d'excellence en santé et en services sociaux (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]

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 [Cardiac Care Network of Ontario (CCN) et Ministry of Health and Long-Term Care (MOHLTC), 2014]

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

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 [Ministère de la Santé et des Services sociaux (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 [Haute Autorité de Santé (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]

TABLEAUX D'EXTRACTION DES DOCUMENTS SOURCES

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter : • Que l'implantation valvulaire aortique par cathéter soit faite par des centres désignés seulement. o Le MSSS a limité le nombre de centres désignés à six pour le Québec, soit : l'Institut de cardiologie de Montréal, l'Institut universitaire de cardiologie et de pneumologie de Québec, le Centre hospitalier de l'Université de Montréal, le Centre hospitalier universitaire de Sherbrooke, le Centre universitaire de santé McGill et l'Hôpital du Sacré-Coeur de Montréal. o Une autorisation du MSSS est un préalable à la mise sur pied d'un nouveau programme.
	HAS 2015 Les critères d'encadrement des centres en vigueur tels que définis par l'arrêté du 3 juillet 2012, oblige à ce que : • l'établissement de santé soit titulaire d'une autorisation d'activité de chirurgie cardiaque et d'une autorisation d'activité interventionnelle sous imagerie médicale, par voie endovasculaire, en cardiologie; • les contrôles du respect de ces critères par les établissements répondant aux conditions définies sont assurés par les agences régionales de santé.
Énoncé retenu par le comité:	**1.1.1. Chaque centre qui procède à des implantations valvulaires aortiques doit faire l'objet d'une désignation spécifique du MSSS et une autorisation du MSSS est un préalable à la mise sur pied d'un nouveau programme.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	AATS/ACCF/SCAI/STS 2012 By their very nature, these complex procedures should only be performed in institutions that currently and routinely perform large volumes of surgical aortic valve operations with outcomes that equal or exceed those established nationally for similar procedures. The institution should have an active valvular heart disease surgical program with at least 2 institutionally-based cardiac surgeons experienced in valvular surgery (more than 50% time at hospital with surgical program) Institutional interventional program 1000 cath/400 PCI per year* 50 Total AVR per year of which at least 10 aortic valve replacement (AVR) should be high risk (STS score 6)
	CCS 2012 TAVI should be performed in centres with: a. Established clinical excellence b. A large experience in high risk aortic valve surgery c. A commitment to a comprehensive valve program d. A strong, collaborative multidisciplinary Heart Team e. The ability to provide ongoing quality improvement f. The ability to participate in ongoing research (Strong Recommendation, Low-Quality Evidence).
	ESC/EACTS 2012 TAVI should only be performed in hospitals with cardiac surgery on-site. Class I level C
	AHA/ACC 2014 The optimal care of the patient with complex heart disease is best performed in centers that can provide all available options for diagnosis and management, including the expertise for complex aortic or mitral valve repair, aortic surgery, and transcatheter therapies
	HAS 2015 > 200 remplacements valvulaires aortiques chirurgicaux sur les 12 mois précédant la pose de TAVI
	CSANZ/ANZSCTS 2015 TAVI programs should be established in high volume cardiac surgical centres where on site valve surgery is performed. 50 Total AVR per year of which at least 10 aortic valve replacement (AVR) should be high-risk (STS score 6)
Énoncé retenu par le comité:	**1.1.2. Les interventions TAVI devraient être effectuées uniquement dans des centres :** • **dotés d'un programme de chirurgie cardiaque dont le dont le volume annuel est d'au moins 75 SAVR;** • **ayant une équipe multidisciplinaire dont la composition correspond à celle énoncée dans les normes 1.2.1. et 1.2.2.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	AATS/ACCF/SCAI/STS 2012 Institutional interventional program 1000 cath/400 PCI per year with acceptable outcomes for conventional procedures compared to NCDR benchmarks.
	CSANZ/ANZSCTS 2015 The following activity levels for institutions undertaking TAVI programs are suggested: Minimum of two institutionally-based cardiac surgeons in program Institutional interventional program 1000 cath/400 PCI per year*
Énoncé retenu par le comité:	**1.1.3 Les interventions TAVI devraient être effectuées uniquement dans des centres :** • **dotés d'un programme de cardiologie interventionnelle dont le volume d'activités est d'au-moins 1000 cathétérismes cardiaques et 400 interventions coronaires percutanées;** • **ayant une équipe multidisciplinaire dont la composition correspond à celle énoncée dans les normes 1.2.1. et 1.2.2.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	INESSS 2012 Un espace approprié destiné à la pratique de l'intervention est nécessaire
	CCS 2012 TAVI programs should have ready access to: a. TTE and TEE b. MSCT c. A specially equipped cardiac catheterization lab or hybrid operating room d. Cardiac surgery e. Perfusion services f. A surgical recovery area g. An intensive care unit h. Renal replacement therapy i. Vascular surgery j. Peripheral vascular interventional expertise (Strong Recommendation, Moderate-Quality Evidence).
	AATS/ACCF/SCAI/STS 2012 The institution should contain a full range of diagnostic imaging and therapeutic facilities including: 1. Cardiac catheterization laboratory or hybrid operating room (OR)/cath lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering catheterization laboratory quality imaging. A biplane unit may be advantageous, particularly for congenital heart disease. 2. Noninvasive imaging a. Echocardiographic laboratory. Transthoracic and transesophageal echocardiographic capabilities with sonographers and echocardiographers experienced in valvular heart disease. Access to 3D echocardiography is preferable. b. Vascular laboratory (noninvasive) with vascular specialists capable of performing and interpreting vascular studies. c. CT laboratory with CT technologists and specialists who can acquire and interpret cardiac CT studies. Physical space—The implantation suite must have a sterile environment that meets OR standards. Furthermore, it must have sufficient space to accommodate the necessary equipment for uncomplicated implantations as well as any additional equipment that may be necessary in the event of complications. This includes space for anesthesiology, echocardiography, and cardiopulmonary bypass equipment and personnel. A specifically designed hybrid OR interventional suite is ideal; however, in the absence of such a facility, the interventional cardiac suite should have:

	a. Circulating heating, ventilation, and air conditioning laminar flow diffusers (providing smooth, undisturbed air flow and usually placed directly over the procedure table) to meet air requirements for surgery rooms. b. Asymmetrical/symmetrical 6-lamp 2 X 4 troffers (the inverted, usually metal trough suspended from the ceiling as a fixture for fluorescent lighting) to provide adequate high-output lighting for surgical intervention. c. Adequate number of power receptacles that meet surgical equipment requirements. d. Capability of running cardiopulmonary bypass apparatus in the interventional suite. e. Gas outlets for the anesthesia machine. f. Adequate room size to accommodate the standard equipment required in a cardiac catheterization laboratory (eg, high-definition displays and monitors, O2 analyzer, defibrillator/resuscitation cart, O2 supply, suction, compressed air, CO-oximeter, activated clotting time analyzer) g. Minimum room size of 800 square feet (74.3 m2) to accommodate echocardiographic equipment, sonographers, anesthesia equipment, emergency CT surgical team and cardiopulmonary bypass equipment (eg, surgeon, assistant, scrub tech, pump techs), if needed. 4. Fungible equipment—The interventional suite should stock a large variety of fungible equipment, including various access kits, endovascular sheath and introducers ranging from 4 to 26 F in various lengths, a wide range of guide wires for various purposes, cardiac diagnostic and interventional catheters, vascular closure devices, balloon dilatation catheters ranging from 2 to 30 mm in diameter and of various lengths and profiles, bare metal and covered stents (eg, coronary and peripheral), occlusive vascular devices, snares and other retrieval devices, drainage catheters, and various implantable device sizes with their delivery systems. 5. Postprocedure intensive care facility with personnel experienced in managing patients who have undergone conventional open heart valve procedures. 6. Use of mobile C-arm imaging system in an OR is not adequate. 7. HYBRID OR—The ‘‘2012 American College of Cardiology Foundation Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update’’ will outline the specifications for a hybrid Cath Lab/ OR. Though this is preferable, it is not a prerequisite since it is not available at many institutions
	ÖKG/ ÖGTHC 2012 The entire repertoire of appropriate equipment for heart surgery and interventional cardiology should be available. Further basic essentials for transcatheter valve interventions include adequate X-ray equipment and transoesophageal echocardiographic equipment. If a complete cardiac catheterization laboratory is unavailable for transfemoral procedures, the use of a latest generation mobile C-arm an appropriate cardiac surgical operating room might be an acceptable alternative. However, in the intermediate term, all departments performing transcatheter valve interventions should acquire an appropriate hybrid operating room. There is the need for a full cardiac anaesthesia unit suited for all surgical- and catheter-based procedures. Furthermore, the use of mechanical circulatory support

	systems such as the heart-lung machine should be permanently available. Ideally, both systems should be in the theatre dedicated for the operations/ interventions.
	HAS 2015 les plateaux techniques de cardiologie interventionnelle et de chirurgie cardiaque soient situés dans le même bâtiment selon l'une des modalités définies ci-dessous : - s'il s'agit d'une salle hybride, elle a les caractéristiques techniques permettant de réaliser indifféremment des actes de chirurgie cardiaque ou de cardiologie interventionnelle : membrane d'oxygénation extracorporelle (MOEC) et en salle : qualité d'imagerie optimale, caractéristiques d'un site d'anesthésie, traitement de l'air conforme à celui d'un bloc opératoire, condition de température ; - s'il s'agit d'une salle de cathétérisme cardiaque, et quelle que soit la voie d'abord, la salle est conditionnée comme un bloc opératoire de chirurgie cardio-vasculaire en termes d'asepsie et un site d'anesthésie conforme à celui d'un bloc doit être disponible ; - en cas d'intervention en bloc opératoire, la qualité de l'imagerie est analogue à celle d'une salle de cathétérisme cardiaque ; les plateaux techniques susmentionnés permettent la réalisation d'une circulation extracorporelle (CEC) ;
	CSANZ/ANZSCTS 2015 The facilities should include but are not limited to: 1. Cardiac catheterisation laboratory or hybrid operating room (OR) equipped with a fixed radiographic imaging system with high resolution fluoroscopy and facility for cineangiography and haemodynamic monitoring. 2. Non-invasive imaging a. Echocardiographic laboratory with transthoracic and transoesophageal echocardiographic capabilities. Sonographers and echocardiographers experienced in valvular heart disease. b. Access to a vascular laboratory (noninvasive) with vascular specialists capable of performing and interpreting vascular studies. c. Access to a CT angiography laboratory with CT technologists and specialists who can acquire and interpret cardiac CT studies. 3. A sterile environment that meets, at minimum, OR standards or standards necessary for pacemaker/ICD implantation. 4. Sufficient space to accommodate the necessary equipment for implantations, including space for anaesthesia, echocardiography, and cardiopulmonary bypass equipment and personnel. Appropriate equipment for the procedure and for dealing with possible complications including complete heart block, large vessel rupture, pericardial tamponade, and haemodynamic collapse. A post procedure intensive care facility, HDU, or CCU experienced in managing complex cardiac patients, including patients following conventional cardiac surgery.

	The following are desirable, but may not be available in most current interventional cardiology suites: 1. Circulating heating, ventilation, and air conditioning laminar flow diffusers. 2. High-output surgical lighting. 3. Facilities for running cardiopulmonary bypass or extracorporeal membrane oxygenators (ECMO).
	ACC 2017 The location at which the TAVR procedure is performed varies between institutions and has important physical, personnel, and equipment implications. Optimal equipment requirements include a state-of-the-art, large-field-of-view fluoroscopic imaging system with a fixed overhead or floor-mounted system that has positioning capability rather than a portable C-arm system. Imaging programs that can automatically aid in the selection of orthogonal views for imaging during positioning of the valve (e.g., Fusion Imaging) are also desirable. Integration of echocardiographic images, particularly 3D capabilities, is helpful; the availability of MDCT or CMR is a significant advantage, particularly if image fusion—which will become more widely used in the future—is possible. Full catheterization laboratory hemodynamic capability is also required for all procedural rooms, including hybrid rooms. Other necessary resources include cardiopulmonary bypass machines and related ancillary supplies, with an inventory of interventional cardiology equipment for balloon aortic valvuloplasty, coronary balloons, stents, and 0.014-inch wires if coronary occlusion occurs as a complication of device deployment. As vascular access is critical, a variety of peripheral arterial balloons and covered stents for treatment of peripheral vascular complications such as iliac rupture and a variety of vascular closure devices are also important for completion of the procedure. The procedure location should also be fully capable of providing anesthesia services, including advanced airway management, general anesthesia, full hemodynamic monitoring, and administration of vasoactive agents into the central circulation. As can be seen, these requirements mandate specific room sizes and configurations. Such a hybrid room may be situated in a surgical suite or in a large modified catheterization laboratory (approximately ≥800 square feet) with appropriate air handling and air exchange modifications. In the future, as the types and number of procedures increase for the treatment of a variety of structural heart and endovascular disease procedures, it is anticipated that hybrid rooms will become the standard of care for these team-based therapies.

Énoncés retenus par le comité:	**1.1.4. Dans chaque programme qui procède à des interventions TAVI, il devrait y avoir un accès direct (sans recourir à un transfert interhospitalier) aux éléments suivants :** • **Une salle d'opération ou une salle hybride de dimension suffisante pour utiliser l'équipement nécessaire aux implantations, y compris l'espace nécessaire pour l'anesthésie, l'échocardiographie et l'oxygénation par circulation extracorporelle ainsi que le personnel médical et paramédical requis;** • **L'équipement approprié pour l'intervention et pour traiter les complications possibles telles qu'un bloc auriculoventriculaire (AV) complet, la rupture d'un vaisseau important, une tamponnade et un choc cardiogénique ou tout autre complication cardiovasculaire ou pulmonaire;** • **Une salle de soins intensifs post-procédure où le personnel est expérimenté dans la gestion de patients cardiaques complexes y compris les patients ayant bénéficié d'une chirurgie cardiaque conventionnelle.** **1.1.5 Chaque programme qui procède à des interventions TAVI devrait avoir un accès direct aux services suivants :** • **l'échocardiographie transthoracique (ETT) et l'échographie transoesophagienne (ETO);** • **la tomodensitométrie multi-coupes (TDM-MC);** • **support par circulation extracorporelle;** • **un service de perfusionnistes;** • **la thérapie de remplacement rénal;** • **chirurgie vasculaire et procédures vasculaires percutanées.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	INESSS 2012 Il faut consigner l'information liée à l'évaluation de l'admissibilité de tous les patients chez qui on envisage de pratiquer l'intervention. Dans de tels documents, on doit préciser les raisons de leur inopérabilité (non-admissibilité à une chirurgie cardiaque) et les raisons de refus si les patients ne choisissent pas l'intervention par cathéter (études cliniques, documents de consensus, opinion d'experts). Il faut donc prévoir les ressources humaines et financières liées au processus de sélection des patients aux fins de l'intervention, y compris la consignation de l'information requise. Un financement adéquat et particulier est nécessaire afin d'assurer la stabilité et la perennité des programmes d'implantation par cathéter dans les divers centres. Ce financement devra couvrir les coûts liés à la sélection des patients, à l'implantation (y compris le coût de la valve) et au suivi à court et à long terme des patients qui ont reçu un implant.
	AATS/ACCF/SCAI/STS 2012 The institutional commitment required for a successful program goes beyond the necessary space, personnel, and specialized facilities set forth above. The complex and time consuming preprocedure patient triage process and the amount and intensity of postprocedure patient care after discharge are very labor intensive for the physician and nursing staff, as are the informed consents and communications with patients, families, and referring providers. In addition to supporting the core nursing and technical support staff, arrangements between the institution and the physicians need to be structured to reimburse physician efforts dedicated to nonreimbursable hours of clinical care and medical management of the program.
Énoncé retenu par le comité:	**1.1.6. Le programme d'intervention TAVI devrait avoir un soutien administratif, financier, professionnel et logistique non seulement en ce qui concerne la sélection des patients, l'obtention du consentement et la réalisation de l'intervention, mais aussi afin de permettre le suivi du patient, la consignation des informations au dossier, la gestion de la liste d'attente et le maintien d'un registre local des données pertinentes au programme.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.1 Caractéristiques relatives aux structures et processus institutionnels	INESSS 2012 Il semble approprié qu'au moins un cardiologue interventionnel et un chirurgien cardiaque soient disponibles pour l'intervention.
	ÖKG/ ÖGTHC 2012 Any procedure being performed without the close cooperation of the heart surgeon and the cardiologist (and paediatric cardiologist) is regarded as unsatisfactory by both the ÖKG and the ÖGTHC. The availability and presence in the hospital of both the heart surgeon and the interventional cardiologist is deemed absolutely essential for the management of potential peripheral vascular, aortic, coronary, or other complications all of which require the immediate availability and competence of the heart surgeon and the interventional cardiologist.
	HAS 2015 De plus, la HAS rappelle que la composition des équipes est fonction de la voie d'abord utilisée : - Voie Transfémorale Doivent être présents en salle d'intervention un anesthésiste-réanimateur formé à la chirurgie cardiaque, un infirmier anesthésiste et deux opérateurs qualifiés dont au moins un cardiologue interventionnel et en plus doivent être disponibles un cardiologue échographiste et un chirurgien cardio-vasculaire et thoracique ou un chirurgien vasculaire. - Voie Transapicale Doivent être présents en salle d'intervention un anesthésiste-réanimateur formé à la chirurgie cardiaque, un infirmier anesthésiste et deux opérateurs qualifiés dont au moins un chirurgien cardio-vasculaire et thoracique et en plus doivent être disponibles un cardiologue échographiste et un cardiologue interventionnel. - Voie Sous-clavière Doivent être présents en salle d'intervention un anesthésiste-réanimateur formé à la chirurgie cardiaque, un infirmier anesthésiste et deux opérateurs qualifiés dont au moins un chirurgien cardio-vasculaire et thoracique ou un chirurgien vasculaire et en plus doivent être disponibles un cardiologue échographiste et un cardiologue interventionnel. - Voie Aortique directe L'acte concernant la pose d'une bioprothèse valvulaire par voie aortique directe nécessite une mini-sternotomie. Cet acte n'est pas référencé à la CCAM et en l'état actuel des connaissances, cette voie d'abord ne peut être recommandée.
	ACC 2017 In addition to the interventional cardiologist, cardiothoracic surgeon, and cardiovascular anesthesiologist, other personnel required during the TAVR procedure include a cardiovascular imaging specialist, cardiac perfusionists, and other personnel trained in hemodynamic monitoring and able to rapidly deal with procedural complications.
Énoncé retenu par le comité:	**1.1.7. Un cardiologue interventionnel et un chirurgien cardiaque devraient être disponibles sur place au cours de l'intervention TAVI afin de répondre adéquatement à toute éventuelle complication durant la procédure.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.2 Composition de l'équipe multidisciplinaire TAVI	INESSS 2012 Chaque centre doit créer une équipe multidisciplinaire constituée entre autres des professionnels de la santé et des services sociaux suivants : cardiologues, chirurgiens cardiaques, anesthésistes, gériatres, spécialistes en réadaptation et travailleurs sociaux.
	CCS 2012 The multidisciplinary heart team should include: a. Interventional cardiologists b. Cardiac surgeons c. Imaging specialist d. Cardiac anaesthetist e. Experienced nurses (Strong Recommendation, Low-Quality Evidence).
	ESC/EACTS 2012 TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary. Class I level C
	AATS/ACCF/SCAI/STS 2012 The MDT necessary for a TAVR program is highlighted by the collaboration between the interventional cardiologist and cardiac surgeon. The MDT, however, goes well beyond this collaboration, and must include key providers from other physician groups (eg, anesthesiology, radiology, noninvasive cardiology, intensive care). In addition to the individual physicians, other components that extend to various departments are necessary.
	VARC-2 2012 Valve Academic Research Consortium-2 recommends the use of a heart team for patient evaluation. The heart team should consist of at least (interventional) cardiologists, cardiovascular surgeons, and imaging specialists, but its composition is dynamic and can also include anesthesiologists, geriatricians, neurologists, etc.
	CCN 2014 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.
	AHA/ACC 2014 Class I Patients with severe VHD should be evaluated by a multidisciplinary Heart Valve Team when intervention is considered. (Level of Evidence: C) Heart Valve Team composed primarily of a cardiologist and surgeon (including a structural valve interventionist if a catheter-based therapy is being considered). In selected cases, there may be a multidisciplinary, collaborative group of

	caregivers, including cardiologists, structural valve interventionalists, cardiovascular imaging specialists, cardiovascular surgeons, anesthesiologists, and nurses, all of whom have expertise in the management and outcomes of patients with complex VHD.
	CCS QI 2016 The Heart Team should meet minimum requirements of an interventional cardiologist and cardiac surgeon but should ideally be composed of the patient's treating physician, geriatrician or internist, cardiac imaging specialist and TAVI nurse coordinator.
	CSANZ/ANZSCTS 2015 A Heart Team is defined as a multi-disciplinary team of professionals who are charged with the governance of, and accountability for, the decision making and outcomes of the TAVI program within an institution. Typically a Heart Team could include, but is not limited to, the following: Interventional Cardiologist(s) Cardiothoracic Surgeon(s) Imaging Cardiologist (CT, TTE, TOE) / Radiologist TAVI Nurse Case Manager / Co-ordinator General Cardiologist(s) Cardiac Anaesthetist Intensive Care Physician Geriatrician / General Physician Vascular Surgeon
	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter : Que l'évaluation des patients qui pourraient bénéficier d'une implantation valvulaire aortique soit confiée à une équipe multidisciplinaire constituée : - d'un cardiologue interventionniste ; - d'un cardiologue non interventionniste spécialisé, par exemple, en échocardiographie ; - d'un chirurgien cardiaque ; - d'un anesthésiologiste ; - d'un médecin ou d'une infirmière praticienne spécialisée, détenant une expertise en gériatrie - d'une infirmière clinicienne responsable de l'évaluation, de la préparation et du suivi de la clientèle ; - au besoin, d'un interniste, d'un travailleur social, d'un physiothérapeute d'un psychologue et d'un éthicien.
	HAS 2015 Dans ces conditions, la HAS recommande la présence d'un gériatre lors des réunions de concertation multidisciplinaires…

	La HAS insiste sur la nécessité d'évaluer l'indication du remplacement valvulaire aortique lors d'une réunion de concertation disciplinaire. La réunion de concertation pluridisciplinaire doit impliquer un chirurgien cardiaque, un cardiologue interventionnel, un cardiologue clinicien et un anesthésiste-réanimateur.
	ACC 2017 The management of patients with severe AS who are being considered for TAVR is best achieved by a multidisciplinary, collaborative Heart Valve Team that includes cardiologists with expertise in valvular heart disease, structural interventional cardiologists, imaging specialists, cardiovascular surgeons, cardiovascular anesthesiologists, and cardiovascular nursing professionals. In addition, the primary care provider or geriatrician should be involved before and after the TAVR procedure and should assume primary responsibility for patient care starting at 30 days, with the first primary care provider appointment scheduled no later than 3 months after the procedure.
Énoncés retenus par le comité:	**1.2.1. L'équipe multidisciplinaire TAVI doit inclure au minimum un cardiologue interventionniste et un chirurgien cardiaque auxquels, devraient idéalement se joindre un expert en imagerie et le coordonnateur du programme.** **1.2.2. L'équipe multidisciplinaire TAVI devrait avoir accès à de l'expertise médicale et paramédicale complémentaire lorsqu'elle le juge pertinent (ex : anesthésie, gériatrie interniste, et tout autre intervenant au besoin).**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.2 Composition de l'équipe multidisciplinaire TAVI	INESSS 2012 Une équipe multidisciplinaire doit participer à tous les aspects d'un programme d'implantation valvulaire aortique par cathéter, y compris l'évaluation de l'admissibilité des patients, l'intervention elle-même et les soins donnés à la suite de l'intervention. L'équipe doit effectuer l'évaluation de l'état global de chaque patient chez qui on envisage de pratiquer l'intervention par cathéter et décider ou non d'offrir cette intervention après examen des fonctions cognitives, de la fragilité générale et de l'état physique ainsi que toutes autres dimensions pertinentes L'équipe doit considérer, dans son évaluation du patient, toutes les options thérapeutiques et non seulement l'implantation valvulaire aortique par cathéter. Ces options incluent le traitement médical, la dilatation au ballonnet, le remplacement chirurgical et les soins de confort. L'équipe d'évaluation doit se réunir en personne pour délibérer sur les choix thérapeutiques du patient. Lors de telles rencontres, il faut documenter quels sont les membres de l'équipe multidisciplinaire présents et en conserver les procès-verbaux.
	AATS/ACCF/SCAI/STS 2012 Programmatic success depends on the ability of the MDT to function effectively in the best interest of a given patient. To do so, the MDT must work cohesively through the processes of patient selection, procedural planning, procedural conduct, periprocedural care, and longitudinal follow-up. Through each phase of this continuum, the individual skills of the MDT members should be brought to bear on the process. Pro-formas are useful to ensure all information is presented succinctly; minutes of the meeting, including a synopsis of the discussion and the eventual decision, should be recorded. Long-term follow-up of these patients is an important element of the MDT approach.
	VARC-2 2012 The most important role of the heart team is to provide customized management decisions for common and unusual clinical scenarios in terms of patient selection, procedural performance, and complication management.
	CSANZ/ANZSCTS 2015 One of the principle roles of the team is to ensure that patients are adequately evaluated (worked up) and selected for the procedure. This is to ensure all the comorbidities and risks for the patient are evaluated fully and the best treatment option for the patient (medical therapy, traditional surgery or transcatheter valve therapy) is considered. Such decisions should be considered in a formal case conference involving the members of the Heart Team.
	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter :

	Que l'évaluation des patients qui pourraient bénéficier d'une implantation valvulaire aortique soit confiée à une équipe multidisciplinaire. Le rôle de cette équipe sera : - de procéder à l'évaluation, la sélection et le suivi des patients selon les critères établis; - de s'assurer d'une compréhension commune des termes utilisés, notamment l'inopérabilité, le risque chirurgical « élevé »; - d'évaluer les complications spécifiques attribuées à l'implantation valvulaire aortique par cathéter; - de déterminer et de documenter les objectifs et les finalités de l'intervention. Que l'évaluation des patients et le suivi des rencontres soient bien documentés au dossier médical.
	HAS 2015 Dans ces conditions, la HAS recommande la présence d'un gériatre lors des réunions de concertation multidisciplinaires… La HAS insiste sur la nécessité d'évaluer l'indication du remplacement valvulaire aortique lors d'une réunion de concertation disciplinaire. La réunion de concertation pluridisciplinaire doit impliquer un chirurgien cardiaque, un cardiologue interventionnel, un cardiologue clinicien et un anesthésiste-réanimateur.
	ACC 2017 The document also assumes that the Heart Valve Team will be involved with all aspects of the decision-making and delivery of this complex technology. The specific tasks for the Heart Valve Team are to: 1) review the patient's medical condition and the severity of the valve abnormality; 2) determine which interventions are indicated, technically feasible, and reasonable; and 3) discuss benefits and risks of these interventions with the patient and family, keeping in mind their values and preferences. The Heart Valve Team should emphasize that the purpose of valvular intervention is to improve symptoms and/or prolong survival, while minimizing adverse outcomes associated with the intervention.
Énoncé retenu par le comité:	**1.2.3. L'équipe multidisciplinaire devrait se réunir sur une base régulière afin de participer, de façon concertée, à tous les aspects d'un programme d'intervention TAVI soit l'élaboration d'un plan de soins propre à chaque patient qui comprend la considération de toutes les options thérapeutiques, l'évaluation de l'admissibilité, l'intervention elle-même et les soins donnés à la suite de l'intervention de même que le plan de suivi à long terme.** **Un compte-rendu des décisions prises lors de ces réunions doit être rédigé afin d'assurer la traçabilité de l'information.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.3 Formation/compétence	INESSS 2012 Une formation appropriée à l'intention du personnel de l'équipe multidisciplinaire est nécessaire concernant l'évaluation de l'admissibilité ainsi que la réalisation de l'intervention selon les normes de qualité reconnus par les associations de professionnels et par les normes d'accréditation des établissements.
	CCS 2012 Primary operators should perform a minimum of 25 cases per year (Strong Recommendation, Low-Quality Evidence). Training of a TAVI operator should include: a. Didactic theoretical sessions for 1 day, as a minimum b. Simulator training c. Observation of 2 to 5 TAVI cases, as a minimum d. Support for the initial 5 to 10 cases by a proctor, as a minimum e. New physicians in the field should have performed a 12-month training in structural heart disease, as a minimum (Conditional Recommendation, Low-Quality Evidence).
	AATS/ACCF/SCAI/STS 2012 Minimum requirements for transcatheter valve therapies include an understanding of basic radiation safety necessary for optimal imaging, operator and patient exposure protection, and knowledge of the use of X-ray contrast agents, which may not be standard in cardiac surgery training and experience Training in the use of closed systems for hemodynamic monitoring and contrast injections will result in optimal integration into catheterization laboratories and hybrid environments. Catheter and wire skills, including knowledge of the use of various techniques and the equipment available to access complex anatomy and negotiating necessary vascular and anatomic structures are required. Understanding of the interplay of wires, catheters, and anatomy is required for completion of these procedures Operators should also have experience with specific catheter-based techniques required for valve interventions. Similarly, surgeons should have experience with transapical approaches for left ventricular assist device placement and care of similar high-risk patients to perform transapical TAVR.
	CSANZ/ANZSCTS 2015 While expertise in all of the following is not essential, useful clinical experience for the TAVI interventionist should include : Coronary diagnostic procedures, including left heart catheterisation and the invasive assessment of aortic stenosis Coronary interventions Peripheral vascular diagnostic procedures Peripheral vascular interventions Balloon aortic, mitral, and pulmonic valve dilatation

	Intra-aortic balloon pump (IABP), other cardiac support Large vessel access and closure Surgeons involved in TAVI procedures should be experienced in operating on high-risk surgical AVR patients. The following experience and training is recommended: 100 surgical AVR career, at least 10 of which are ''highrisk'' (STS score————————————————6) or 25 AVR per year or 50 AVR in two years and at least 20 AVR in last year prior to TAVI initiation Experience with, and management of, peripherally inserted cardiopulmonary bypass Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries
	HAS 2015 l'établissement de santé dispose d'équipes médicales et paramédicales préalablement formées à la technique de pose de bioprothèses valvulaires aortiques par voie artérielle transcutanée ou par voie transapicale ; l'établissement de santé dispose de praticiens ayant l'expérience du franchissement du rétrécissement aortique serré et de la valvuloplastie par ballonnet ou une expérience des techniques de mise en place des endoprothèses aortiques thoraciques couvertes ou des membranes d'oxygénation extracorporelle percutanées ;
Énoncé retenu par le comité:	**1.3.1. Afin de réaliser l'intervention en tant qu'opérateur primaire, les chirurgiens cardiaques et les cardiologues interventionnistes devraient avoir reçu une formation spécifique au dispositif employé de même qu'avoir été supervisés et jugés aptes à procéder de façon autonome par un expert (proctorship).**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.3 Formation/compétence	CCS 2012 Institutions should perform a minimum of 25-50 cases per year (Strong Recommendation, Low-Quality Evidence).
	AATS/ACCF/SCAI/STS 2012 Centers should be approved for transcatheter aortic valve programs based on a minimum number of cases per year, and perioperative and 1-year outcomes above a minimum threshold. Programs in existence<18 months: 2 per month
	CSANZ/ANZSCTS 2015 The following minimum volume and outcomes requirements are recommended for approved TAVI programs. Program volume of 20 TAVI per year or 40 per two years
	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter : Que le maintien d'un programme d'implantation valvulaire aortique par cathéter soit conditionnel à la réalisation annuelle d'un minimum de 30 procédures répondant aux critères fixés afin de maintenir le niveau d'expertise requis des équipes soignantes.
	HAS 2015 Les agences contrôlent également que l'établissement de santé réalise au moins vingt-quatre implantations de bioprothèses valvulaires aortiques par voie artérielle transcutanée ou par voie transapicale sur douze mois.
Énoncé retenu par le comité:	**1.3.2. Afin de maintenir le niveau d'expertise requise des équipes soignantes :** • **un programme interventions TAVI devrait réaliser un minimum annuel de 30 procédures;** • **au niveau individuel, les cliniciens devraient réaliser un minimum annuel de 20 procédures en tant qu'opérateur primaire ou secondaire.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.4 Délais et liste d'attente	CCN 2014 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.
	CCS QI 2016 Les temps d'attente pour l'intervention TAVI refléteront la capacité des centres de procéder à des évaluations en temps opportun et de fournir l'accès à l'intervention dans un laps de temps approprié. I. Délai d'évaluation pour l'intervention de remplacement valvulaire aortique par cathétérisme (TAVI), défini comme la période allant du moment où le patient est orienté vers l'équipe de l'intervention TAVI, jusqu'à la décision de l'équipe de cardiologie. II. Temps d'attente pour l'intervention TAVI, défini comme le délai entre la « date de la décision de l'équipe de cardiologie » (c.-à-d., une recommandation consensuelle sur le traitement par l'intervention TAVI, ET le patient est prêt, consentant et capable) et la « date de l'intervention ».
Énoncé retenu par le comité:	**1.4.1. Par souci d'uniformité, le programme d'intervention TAVI devrait utiliser les définitions de la société canadienne de cardiologie dans la consignation des données relatives aux temps d'attente :** • **délai encouru pour procéder à l'évaluation du patient en vue de l'éventuelle intervention à partir du moment où l'équipe multidisciplinaire TAVI est saisie du dossier;** • **délai encouru pour procéder à la réalisation de l'intervention à partir du moment où l'équipe multidisciplinaire TAVI a émis sa recommandation de procéder à l'intervention.** **Le programme devrait également documenter l'ordre de priorité des patients sur la liste d'attente.** **Dans le cas où un patient consulte dans le but d'obtenir une seconde opinion, une communication avec le centre ayant émis le premier avis devrait être établie.**

1. Normes organisationnelles relatives à un programme d'implantation valvulaire aortique par cathéter	
1.5 Registre de données	INESSS 2012 Le personnel des centres doit assurer le suivi des patients ayant subi une implantation par cathéter en mesurant des indicateurs standardisés de bénéfices (p. ex. : qualité de vie, état fonctionnel et cognitif, destination et réadmissions hospitalières après le congé initial), et non seulement la survie, à court et à long terme.
	AATS/ACCF/SCAI/STS 2012 Long-term outcome reporting is obligatory, to track not only survival, but also other parameters including periprocedural complications (CVA, vascular, renal, infectious, etc), aortic regurgitation, the need for reintervention, subsequent surgery, and quality of life. Individual centers are also responsible for critically evaluating their own experience, through local and regional quality improvement initiatives, and for participating in national databases and registries (eg, STS/ACCTVTRegistry) Components of a national/international registry should include preoperative risk factors and valve assessment, intraoperative details, early postoperative morbidity, and late follow-up including survival, need for reintervention, functional class, device related complications, and late assessment of valve performance. It is inappropriate to perform these novel and innovative procedures without the institutional infrastructure to ensure adequate early data collection and later follow-up.
	ÖKG/ ÖGTHC 2012 The Austrian Society of Cardiology (O¨ KG) and the Austrian Society for Thoracic and Cardiovascular Surgery (ÖGTHC) are proposing to establish an aortic valve registry, which is intended to be completed by 1 January 2011. All aortic valve operations and all aortic valve interventions carried out in Austria will be included in the database. The data to be collected will include all surgically performed aortic valve replacements as well as all interventionally performed valve implantations, hence a comprehensive record relating to short- and long-term results will be compiled. Participation in the compilation of the registry should be strongly recommended, and indeed should be made obligatory.
	CCN 2014 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). 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. **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. **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.
	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter : Que chaque centre procédant à des implantations valvulaires aortiques maintienne un registre local permettant l'évaluation des effets à court, moyen et long termes de l'utilisation de ces dispositifs sur l'état de santé des patients ainsi que sur leur qualité de vie. Que L'INESSS et le RQCT, en collaboration avec les centres désignés, déterminent le contenu des registres locaux afin d'uniformiser les données recueillies, par exemple : critère de choix, modes d'intervention choisis, risques identifiés,

	complications et résultats cliniques. Que chaque centre désigné s'engage formellement à collaborer avec l'INESSS et le RQCT dans le cadre des études rétrospectives dont les objectifs principaux seront d'évaluer la qualité de l'évaluation, de la sélection et du suivi de la clientèle, selon les critères qui auront été établis par les experts et reconnu par le MSSS et d'évaluer les effets à court, moyen et long termes de ce traitement sur la santé et la qualité de vie de la clientèle ainsi que les critères d'évaluation, de sélections et de suivi de la clientèle.
	CCS QI 2016 MORTALITÉ À 30 JOURS ET À 1 AN APRÈS LE TAVI La mortalité est considérée comme une mesure importante de la qualité des soins et de la sélection appropriée des patients pour le remplacement valvulaire aortique par cathétérisme. ÉVALUATION DE LA QUALITÉ DE VIE La capacité de prolonger la vie du remplacement valvulaire aortique par cathétérisme pourrait être limitée dans une population à risque élevé, en raison de la présence de comorbidités multiples. C'est pourquoi il est important d'évaluer la qualité de vie du patient après une telle intervention afin d'examiner les bienfaits cliniques. TAUX DE RÉADMISSION, TOUTES CAUSES CONFONDUES, DANS LES 30 JOURS APRÈS UNE INTERVENTION TAVI On vise maintenant davantage les taux de réadmission dans les 30 jours comme mesure d'évaluation de la qualité des soins actifs. TAUX DE RÉADMISSION À L'HÔPITAL DANS L'ANNÉE, TOUTES CAUSES CONFONDUES Le taux de réadmission est considéré comme une mesure importante de la qualité des soins et de la sélection appropriée des patients pour le remplacement valvulaire aortique par cathétérisme.
	MSSS 2015 Le ministère de la Santé et des services sociaux formule les orientations ministérielles suivantes sur l'implantation valvulaire aortique par cathéter : • Que chaque centre procédant à des implantations valvulaires aortiques maintienne un registre local permettant l'évaluation des effets à court, moyen et long termes de l'utilisation de ces dispositifs sur l'état de santé des patients ainsi que sur leur qualité de vie.
	ACC 2017 Repeat echocardiography is recommended at 30 days and then at least annually to 1) comply with current requirements for following TAVR patients in a registry, 2) monitor for complications of TAVR, and 3) guide medical therapy of concurrent cardiac conditions, including guideline-recommended medical treatment for LV dysfunction.
Énoncé retenu par le comité:	**1.5.1 Chaque centre qui réalise des interventions TAVI devrait maintenir une base de données locale des paramètres pertinents au programme selon les normes et indicateurs de qualité qui auront été établis pour le Québec. Dans cette base de données, devraient figurer tous les patients évalués par l'équipe multidisciplinaire TAVI, que l'option thérapeutique retenue ait été le RVA, l'implantation valvulaire aortique par cathéter ou le traitement médical. Chaque centre devrait également effectuer un suivi des résultats cliniques obtenus au moyen d'une révision annuelle.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	CCS 2012 For evaluation of TAVI candidates: 1. Screening for TAVI should include all of the following: a. A comprehensive assessment of medical history b. A complete physical examination with special attention to signs of severe AS, lung disease, and peripheral artery disease; objective evaluation of neurocognitive function and frailty is encouraged; exercise testing or standardized walk tests may be helpful c. Electrocardiogram, chest X ray, complete blood count, electrolytes, creatinine, liver function; brain natriuretic peptide may be helpful d. TTE with an assessment of annulus diameter; low-dose dobutamine stress echocardiography may be helpful in patients with severely reduced LV function and a low transaortic gradient e. TEE to assess the annulus diameter is recommended, particularly in the absence of MSCT measurements f. Coronary angiography g. Aortography and ilio-femoral invasive angiography or MSCT angiography, preferably both h. Accurate measurement of aortic annulus size by TEE and/or MSCT or MRI is key for appropriate selection of prosthesis size (Strong Recommendation, Weak Evidence).
	CCN 2014 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).

	AHA/ACC 2014 Class I TTE is recommended in the initial evaluation of patients with known or suspected VHD to confirm the diagnosis, establish etiology, determine severity, assess hemodynamic consequences, determine prognosis, and evaluate for timing of intervention (Level of Evidence: B)
	ACC 2017 5.1.2.1. Aortic Stenosis Symptoms and Severity The initial assessment of the patient includes evaluation of AS symptoms, disease severity, and standard clinical data as well as determination of major cardiovascular and noncardiovascular comorbidities. Echocardiographic measures of AS severity should be reviewed, disease severity confirmed, and additional imaging performed as indicated.
Énoncé retenu par le comité:	**2.1.1. L'évaluation préopératoire devrait être consignée au dossier et comprendre minimalement:** • **les symptômes et la gravité de la sténose aortique;** • **l'évaluation de critères anatomiques nécessaires à la détermination des dimensions de l'anneau valvulaire, de l'implant approprié ainsi que de la voie d'approche à privilégier;** • **l'évaluation de critères anatomiques constituants une contrindication à l'approche chirurgicale telle que: aorte de porcelaine, pontage accolé au sternum et thorax hostile;** • **la revue des interventions précédentes le cas-échéant;** • **les autres comorbidités pertinentes.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	ACC 2017 5.1.2.3. Major Cardiovascular Comorbidity Previous cardiac surgical procedures or transcatheter interventions should be reviewed as these may be pertinent to the intervention being planned. Diagnostic tests aid in evaluating major cardiovascular comorbidities that might impact treatment decisions. Coronary angiography is indicated in all patients because coronary artery disease is common in patients undergoing TAVR (40-75%). Other conditions that might increase procedural risk or limit the benefit of the procedure include LV systolic or diastolic dysfunction, severe mitral regurgitation (MR) or mitral stenosis, and severe pulmonary hypertension, all of which can be evaluated by echocardiography. Although low ejection fraction has traditionally been identified as a risk marker for poor outcomes after TAVR, recent studies suggest low flow—defined as stroke volume index less than 35 mL/m2—may also be associated with poor outcomes post-TAVR regardless of ejection fraction (7,8). Therefore, both stroke volume index and ejection fraction should be considered for patient selection in TAVR because these patients have poor outcomes regardless of management strategy. The presence of significant mitral valve (MV) disease in patients with severe AS can complicate the decision for TAVR and warrants careful consideration. Some low-risk candidates for AVR have anatomical factors that increase the risk of surgery. These include prior mediastinal irradiation, chest wall abnormalities, and previous surgical procedures, which result in bypass grafts or vital mediastinal structures being fused to the undersurface of the sternum. In addition to post-treatment scarring from prior irradiation, other effects of radiation on the heart reduce the benefits of aortic valve interventions, including concurrent MV disease, coronary artery disease, myocardial dysfunction, and pericardial involvement. The presence of a "porcelain aorta" is a relative contraindication for SAVR, so TAVR is preferred in patients with this anatomy (10). The anatomy and size of peripheral vessels and the presence of atherosclerosis are important in decision-making about access routes for TAVR and may influence the decision to proceed with SAVR versus TAVR.
	Puri 2016

Table I Medical comorbidities and factors predicting poorer outcomes post-transcatheter aortic valve implantation

Medical comorbidity	Factors specifically associated with futility
CLD	6MWT < 150 m[13] Oxygen-dependency[14]
Advanced CKD	Atrial fibrillation[21] Dialysis dependence[21]
Frailty	>2 frailty indices (Katz activities of daily living + mobility status[a])[30]
Cardiovascular conditions	LVEF < 30% Pre-capillary or combined PH[b] (mean PAP > 25 mmHg)[44] Low trans-aortic gradient Impaired contractile reserve Low flow state (<35 mL/m^2)[40] Organic severe MR

6MWT, 6-min walk test; LVEF, left ventricular ejection fraction; PH, pulmonary hypertension; PAP, pulmonary artery pressures; MR, mitral regurgitation.
[a]Time taken to walk 5 m is >6 s.
Katz indices are: independence in feeding, bathing, dressing, transferring, toileting, urinary incontinence.
[b]Measured invasively. Combined PH defined as post-capillary PH (measured by LV end-diastolic pressure > 15 mmHg) with a diastolic pulmonary artery pressure ≥ 7 mmHg than LV end-diastolic pressure.

Énoncé retenu par le comité:

2.1.2. L'évaluation préopératoire devrait être consignée au dossier et comprendre une évaluation de la fonction cardiaque globale avec une attention particulière aux facteurs cardiovasculaires suivants associés à des résultats défavorables, y compris :

- **classe fonctionnelle IV de la New York Heart Association (NYHA);**
- **indices de dysfonction ventriculaire gauche :**
  - **fraction d'éjection ventriculaire gauche;**
  - **indice du volume d'éjection (stroke volume index);**

	• **hypertension artérielle pulmonaire sévère;** • **fibrillation auriculaire ou autres arythmies pertinentes;** • **présence de valvulopathies associées;** • **maladie vasculaire périphérique.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	ACC 2017 5.1.2.4. Major Noncardiovascular Comorbidity Patients should be evaluated for major noncardiovascular comorbidities, including active malignancy with limited life expectancy; gastrointestinal disease such as inflammatory bowel disease, cirrhosis, varices; active gastrointestinal bleeding with limited ability to take antiplatelet and anticoagulant agents; severe chronic kidney disease (estimated glomerular filtration rate [eGFR] <30mL/min or dialysis); severe pulmonary disease (oxygen dependence, forced expiratory volume-1 second [FEV1]<50% predicted, or diffusing capacity of the lungs for carbon monoxide [DLCO]<50% predicted), and neurological disorders such as movement disorders and dementia (for example, Mini Mental State Examination [MMSE] score <24). A very prevalent and important comorbidity is chronic lung disease, which remains an independent predictor of poor outcomes post-TAVR. Patients with oxygen-dependent chronic obstructive pulmonary disease and very low FEV1 values (<30% predicted) have poor life expectancy, independent of severity of AS. The utility of TAVR in such patients should be carefully considered.
	Puri 2016 **Table I Medical comorbidities and factors predicting poorer outcomes post-transcatheter aortic valve implantation** **Medical comorbidity** / **Factors specifically associated with futility** CLD: 6MWT < 150 m[13]; Oxygen-dependency[14] Advanced CKD: Atrial fibrillation[21]; Dialysis dependence[21] Frailty: >2 frailty indices (Katz activities of daily living + mobility status[a])[30] Cardiovascular conditions: LVEF < 30%; Pre-capillary or combined PH[b] (mean PAP > 25 mmHg)[44]; Low trans-aortic gradient; Impaired contractile reserve; Low flow state (<35 mL/m^2)[40]; Organic severe MR 6MWT, 6-min walk test; LVEF, left ventricular ejection fraction; PH, pulmonary hypertension; PAP, pulmonary artery pressures; MR, mitral regurgitation. [a]Time taken to walk 5 m is >6 s. Katz indices are: independence in feeding, bathing, dressing, transferring, toileting, urinary incontinence. [b]Measured invasively. Combined PH defined as post-capillary PH (measured by LV end-diastolic pressure > 15 mmHg) with a diastolic pulmonary artery pressure ≥ 7 mmHg than LV end-diastolic pressure.

Énoncé retenu par le comité:	**2.1.3. L'évaluation préopératoire devrait être consignée au dossier et porter une attention particulière aux facteurs non cardiovasculaires suivants associés à des résultats défavorables, y compris :** • **néoplasie active avec une espérance de vie limitée;** • **maladie rénale chronique sévère (taux de filtration glomérulaire estimé [EGFR] : < 30 ml / min ou dialyse);** • **maladie pulmonaire sévère (dépendance à l'oxygène, volume expiratoire seconde [FEV1] : < 50 % prédit ou capacité pulmonaire de diffusion du monoxyde de carbone [DLCO] : < 50 % prédit);** • **diabète grave accompagné de complications multiples;** • **désordre neurologique dégénératif qui limite de façon importante la mobilité ou l'espérance de vie;** • **maladies inflammatoires de l'intestin;** • **cirrhose, varices oesophagiennes, saignements gastro-intestinaux actifs accompagnés d'une capacité limitée à prendre des antiplaquettaires et des agents anticoagulants;** • **perte de poids involontaire;** • **indice de masse corporelle (IMC) < 18,5.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients

2.1 Évaluation préopératoire

ESC/EACTS 2012

Use of the STS scoring system >10% may result in a more realistic assessment of operative risk

AHA/ACC 2014

Procedure-Specific Impediments

	Low Risk (Must Meet ALL Criteria in This Column)	**Intermediate Risk (Any 1 Criterion in This Column)**	**High Risk (Any 1 Criterion in This Column)**	**Prohibitive Risk (Any 1 Criterion in This Column)**
STS PROM*	<4% **AND**	4% to 8% **OR**	>8% **OR**	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y **OR**
Frailty†	None **AND**	1 Index (mild) **OR**	≥2 Indices (moderate to severe)	
Major organ system compromise not to be improved postoperatively‡	None **AND**	1 Organ system **OR**	No more than 2 organ systems **OR**	≥3 Organ systems **OR**
Procedure-specific impediment§	None	Possible procedure- specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

*Use of the STS PROM to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within 1 standard deviation of STS average observed/expected ratio for the procedure in question.

†Seven frailty indices: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) and independence in ambulation (no walking aid or assist required or 5-meter walk in <6 s). Other scoring systems can be applied to calculate no, mild-, or moderate-to-severe frailty.

‡Examples of major organ system compromise: Cardiac—severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEV1 <50% or $DLCO_2$ <50% of predicted; CNS dysfunction (dementia, Alzheimer's disease, Parkinson's disease, CVA with persistent physical limitation); GI dysfunction—Crohn's disease, ulcerative colitis, nutritional impairment, or serum albumin <3.0; cancer—active malignancy; and liver—any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

§Examples: tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to r chest wall, or radiation damage.

	CCS QI 2016 En l'absence d'un score de risque propre à l'intervention TAVI, une certaine évaluation du risque doit être documentée pour chaque patient et, en conséquence, conformément aux recommandations de VARC-2, l'utilisation du score de la STS est fortement recommandée.
	ACC 2017 Estimates of risk in patients referred for TAVR require consideration of the whole patient and several prognostic variables. Individual patient risk assessment combines the STS risk estimate, frailty, major organ system dysfunction, and procedure-specific impediments (see Table 7, Section 2.5 in the 2014 AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease). The STS risk score is an accepted tool to predict the 30-day risk of SAVR and serves as a starting point for risk assessment in TAVR candidates. Three categories of risk are identified on the basis of the STS score: <4% (low risk), 4-8% (intermediate risk), and >8% (high risk). Despite its broad use and its accuracy regarding the risk of SAVR, the STS score has several limitations in risk assessment among elderly patients being considered for TAVR. Specifically, it does not include such indices as frailty; degree of disability; echocardiographic variables such as low-flow AS and pulmonary hypertension; and other comorbidities such as liver disease or hostile chest, among others. A TAVR-specific risk score for predicting patient level in-hospital mortality has recently been developed and validated from the STS/ACC/TVT Registry (26). Although this score yields slightly improved discrimination over the STS score and calibration is adequate, it is still limited by a lack of consideration of frailty, disability, and cognitive function. The optimal measure of outcome after TAVR has not been clearly defined but quality of life following the TAVR procedure as well as mortality should be considered (27). Currently the AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease recommends a risk assessment scheme based on the STS risk score, frailty, comorbidity, and procedure-specific impediments, and classifies patients with severe AS into 4 global risk categories (see Section 2.5 in 2014 Guidelines): 1. Low risk: STS <4% with no frailty, no comorbidity, and no procedure-specific impediments. 2. Intermediate risk: STS 4-8% with no more than mild frailty or 1 major organ system compromise not to be improved postoperatively and minimal procedure-specific impediments 3. High risk: STS >8%, or moderate-severe frailty, no more than 2 major organ system compromise not to be improved postoperatively, or a possible procedure-specific impediment. 4. Prohibitive risk: Preoperative risk of mortality and morbidity >50% at 1 year or ≥3 major organ system compromise not to be improved postoperatively or severe frailty or severe procedure specific impediments.
Énoncé retenu par le comité:	**2.1.4. L'évaluation préopératoire devrait être consignée au dossier et comprendre :** • **une évaluation du risque chirurgical selon l'échelle de la Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM);** • **une évaluation de la classe fonctionnelle selon l'échelle de la New York Heart Association (NYHA).**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	INESSS 2012 Processus de sélection des patients Une équipe multidisciplinaire, qui comprend des cardiologues et des chirurgiens cardiaques, doit effectuer l'évaluation de l'état global de chaque patient et décider d'offrir cette intervention après avoir examiné les fonctions cognitives, la fragilité générale et l'état physique ainsi que toutes autres dimensions pertinentes. Puisque la majorité des patients orientés vers cette intervention seront âgés, l'implication active d'un gériatre est tout à fait pertinente.
	CCS 2012 Neurocognitive functions are commonly assessed with the use of various standardized objective measures (eg, Mini Mental State Examination, clock test) as is frailty.
	ESC/EACTS 2012 Specific validated scores enable the assessment of cognitive and functional capacities which have important prognostic implications in the elderly. The expertise of geriatricians is particularly helpful in this setting.
	VARC-2 2012 Baseline evaluation of the presence of cognitive dysfunction (mild cognitive impairment or dementia) has also emerged as an essential part of the initial risk stratification, especially in older populations, where the risk, benefit, and cost-effectiveness of invasive procedures must be weighed judiciously. Preprocedural cognitive assessment may also help avoid attributing postprocedural mental status changes to stroke categories. Among the several clinically established rating scales (eg, Mini-Mental State Examination, modified Telephone Interview of Cognitive Status [TICS-M], Clinical Dementia Rating Scale),12 there is no particular standard for TAVI. Nevertheless, some systematic cognitive assessment by neuropsychological experts should be a part of the initial heart team evaluation.
	Puri 2016 … there is an emerging consensus of the importance of a more holistic, multidisciplinary approach to pre-TAVI patient assessment, with careful attention to baseline frailty, mobility and cognition, in addition to a variety of comorbid medical conditions.
	ACC 2017 Cognitive function should be assessed using validated tools to screen for prior disabling stroke, cognitive impairment or dementia, and depression. The Mini Mental State Examination can be used to identify those with dementia, with scores <24 being abnormal (22). While cognitive function following TAVR is preserved in most (23), assessment can establish baseline cognitive reserve prior to the procedure. Depression is a confounder of cognitive performance; thus a history followed by a validated tool such as the Center for Epidemiologic Studies Depression Scale is warranted (24).

Énoncé retenu par le comité:	**2.1.5. L'évaluation des fonctions cognitives devrait être consignée au dossier du patient.** **En présence d'indices d'altération possible, l'évaluation devrait être objectivée au moyen de l'administration d'un ou plusieurs test(s) validé(s).**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	INESSS 2012 Une équipe multidisciplinaire, qui comprend des cardiologues et des chirurgiens cardiaques, doit effectuer l'évaluation de l'état global de chaque patient chez qui on envisage de pratiquer l'intervention par cathéter et décider ou non d'offrir cette intervention après examen des fonctions cognitives, de la fragilité générale et de l'état physique ainsi que toutes autres dimensions pertinentes.
	AHA 2014 A number of mechanisms to evaluate frailty assess the ability to perform activities of daily living (independence in feeding, bathing, dressing, transferring, toileting, urinary continence, etc.) and measurements of gait speed, grip strength, and muscle mass. Published frailty scores are available, but a limited evaluation may use the following: no frailty (able to perform all activities of daily living and perform a 5-meter walk in <6 seconds), mild degree of frailty (unable to perform 1 activity of daily living or unable to perform a 5-meter walk in <6 seconds), and moderate-to-severe degree of frailty (unable to perform ≥2 activities of daily living). Further research is required to enhance the predictive accuracy of current risk scores, particularly in patients undergoing transcatheter therapy.
	ACC 2017 5.1.3. Functional Assessment 5.1.3.1. Frailty and Disability A comprehensive evaluation includes assessments of frailty, physical function, independence in activities of daily living (ADLs) (e.g., feeding, bathing, dressing, transferring, toileting), and cognitive function (11). An evaluation should start with screening for independence, cognitive function, and slow walking speed (gait speed—3 timed trials over a 5-meter distance). Those with gait speed >0.83m/s and preserved cognition and independence are likely not frail, but those with gait speed <0.5m/sec or with gait speed <0.83m/s with disability or cognitive impairment need further evaluation. Additional assessment can be informed by qualitative rating scales like the Canadian Study of Health and Aging Scale, performance-based assessments like the 'Up and Go' test and chair stands, deficit accumulation summary measures like the Rockwood Frailty Index, or frailty phenotype scales like the Cardiovascular Health Study Frailty Scale or Edmonton Frail Scale (12-18). Nutritional deficiency (body mass index <21 or albumin <3.5g/dL), risk for malnutrition (score ≤11 on Mini Nutritional Assessment), or weight loss (>10lb decline in 1 year) add information on energy intake and consumption (19). The patient can be classified as not frail, pre-frail, or frail with varying severity as an aggregate clinical assessment based on tests performed (20). 5.1.3.2. Physical Functioning In addition, the 6-minute walk test should be utilized to assess the physical functioning and endurance of the patient (21). This test provides predictive information on the likely benefit, long-term mortality, and functional outcomes of patients undergoing TAVR. Independence in basic activities of daily living also informs baseline functional ability and can provide

	information on post-procedural care needs. These tests are ideally performed in an outpatient setting since results may differ in an inpatient admission setting.
Énoncé retenu par le comité:	**2.1.6. L'évaluation fonctionnelle devrait être consignée au dossier du patient et comprendre une évaluation du niveau d'indépendance dans l'exécution des activités de la vie quotidienne de base (alimentation, hygiène, élimination, bain et habillage).** **En présence d'indices d'altération possible, l'évaluation devrait être objectivée au moyen de l'administration d'un ou plusieurs test(s) validé(s).**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	INESSS 2012 Une équipe multidisciplinaire, qui comprend des cardiologues et des chirurgiens cardiaques, doit effectuer l'évaluation de l'état global de chaque patient chez qui on envisage de pratiquer l'intervention par cathéter et décider ou non d'offrir cette intervention après examen des fonctions cognitives, de la fragilité générale et de l'état physique ainsi que toutes autres dimensions pertinentes
	AHA/ACC 2014 The choice of proceeding with surgical versus transcatheter AVR is based on multiple parameters, including the risk of operation, patient frailty, and comorbid conditions.

Hinterbuchner 2016

Besides anatomical considerations, targeted evaluation of comorbidities, surgical risk stratification and frailty assessment is pivotal for choosing the right treatment option for each potential patient (TAVR, surgical aortic valve replacement (SAVR) or medical treatment).

Table 2. Frailty assessment tools and their use in TAVR studies.

Frailty Instruments	Description	Scoring	TAVI studies	Comments / Discrepancies
Rockwood Frailty Scale	number of health deficits from the 7-item CSHA frailty index	very fit (1) to severely frail (7)	Seiffert et al.[17]	⩾ 6 moderate or more severe frail
Fried Phenotype Frailty Assessment (FFS)	**shrinking** weight loss	⩾10 lbs or 4.5 kg over the last year	Green et al.[22]	assessment loosely parallel to FFS including gait speed (5MWT) and grip strength, divided into quartiles, 0–3 points for frailty score
	slowness 5 meter walk test	⩾6 s (0.76 m/s) for male (>173 cm) and female (>159 cm) ⩾7 s for male (⩽173 cm) and female (⩽159 cm)	Sündermann et al.[21]	a new frailty score (CAF) was developed including FFS but not unintentional weight loss; used 4-MWT to test for gait speed
	weakness handgrip strength test (3x)	in kg, cut-off adjusted for gender and BMI		in the simplified version of CAF = FORECAST none of the FFS domains were included
	exhaustion CES-D questionnaire	self reported		CAVE: IADL=physical activity score covering the Fried low physical activity domain, not the Lawton IADL
	low physical activity using the Minnesota Leisure Time Activity Questionnaire (short version)	men ⩽383 kcal/week women ⩽270 kcal/week		
		non-frail (0/6) to pre-frail (1–2/6), frail (⩾3/6)		
Walk Test (4 Meters, 5 Meters, 10 Meters)	time it takes to walk a distance of 4, 5 or 10 meters as an indicator for slow gait speed	⩾6 s (0.76 m/s) for male (>173 cm) and female (>159 cm) ⩾7 s for male (⩽173 cm) and female (⩽159 cm)	Green et al.[22] Sündermann et al.[21]	5 MWT; in m/s, divided into quartiles; 0–3 points 4 MWT
6 minute walk test	measuring the distance which can be walked in 6 minutes	20–50 meter distance change	Afilalo et al.[18]	5 MWT, 3 times, an average was calculated, patients permitted to use waking aids frailty = slow walkers ⩾6 s fit = normal walkers <6 s
Dominant Hand Grip Strength	measurement of muscle strength as an indicator for weakness	in kg adjusted for age and BMI	Green et al.[22] Sündermann et al.[21]	Jamar™ dynamometer, quartiles stratified by gender, 0–3 points part of the CAF
Timed Get Up and Go (TUG)	time to rise from a chair, walk three meters, turn around, walk back to the chair and sit down as an indicator for mobility	⩽10 s = independent ⩾30 s = dependence	Stortecky et al.[20]	⩾20 s = moderate to severe limitation of mobility <20 s = no or only slight limitation of mobility
		⩾ 13.5 s = high risk for falls	Schoenenberger et al.[19]	⩾20 s = mobility impairment = 1 point assigned for a new defined frailty index
30 second Chair Stand Test (30 CST)	numbers of stand ups form a chair within 30 s	age and gender adjusted ranges	Sündermann et al.[21]	3 x sit to stand, time measured in s (⩽ 11 sec = 0; 11.1–14 sec = 1; 14.1–17 sec = 2; >17 sec = 3; unable = 4 points for the CAF)

(Continued)

Table 2. (Continued)

Frailty Instruments	Description	Scoring	TAVI studies	Comments / Discrepancies
Katz Activity of Daily Life Index	functional assessment for self-reported independency in • feeding • bathing • dressing • transferring • toileting • urinary continence	full function (6), moderate impairment (4) and severe functional impairment (≤2) AHA guidelines*: Katz ADL + independence in ambulation (no walking aid or assist required) or 5MWT <6sec *0=none; 1=mild; ≥2=moderate to severely frail	Green et al.[22] Puls et al.[24] Schoenenberger et al.[19] Kamga et al.[23] Stortecky et al.[20] Afilalo et al.[18]	any dependence = 3 points independent = 0 points 6 = independent <6 = frail ≥1 limited activity = 1 point for the summary frailty score functional decline = decrease of ≥1 point in BADL between baseline and 6-month follow-up basic ADL assessment = modified KATZ index consisted of: eating, hygiene, dressing, toileting, walking not included in the SHERPA ≥1 limited activity = 1 point for MGA score average number of disabilities
Lawton Instrumental Activities of Daily Living Scale (IADL)	self-reported information about functional skills: • telephone • shopping • food preparation • housekeeping • laundry • mode of transportation • responsibility for own medications • ability to handle finances	low function = 0 points = dependent to high function = 8 points = independent	Stortecky et al.[20] Schoenenberger et al.[19] Kamga et al.[23] Afilalo et al.[18]	≥1 limited activity = 1 point for MGA score ≥1 limited activity = 1 point for the summary frailty score included in the SHERPA score; number of autonomous IADL: 6–7 = 0 points; 5 = 1 point; 3–4 = 2 points; 0–2 = 3 points average number of disabilities
Identification of Seniors at Risk (ISAR)	six questions on: • functional dependency • increased need for help • hospitalization < 6 months • impaired memory • impaired vision • drugs ≥ 3 daily	low risk = 0–1 intermediate risk = 2–3 high risk >3	Kamga et al.[23]	no impact on mortality
Serum Albumin (SA)	serum marker for malnutrition and wasting	3.5 to 5.0 g/dL	Green et al.[22] Kamga et al.[23]	g/dL, quartiles, 0–3 points for the frailty score g/dL, no significant difference between survivors and non-survivors
Mini Nutritional Assessment (MNA)	six questions on • food intake • weight loss, • mobility, • psychological stress or acute disease • presence of depression or dementia • BMI as a marker for malnutrition	12–14 points = normal - not at risk 8–11 points = at risk of malnutrition 0–7 points indicate malnutrition	Schoenenberger et al.[19] Stortecky et al.[20]	<12 = 1 point for frailty index <12 = malnutrition probably = 1 point for MGA score ≥12 malnutrition improbable

Table 2. (Continued)

Frailty Instruments	Description	Scoring	TAVI studies	Comments / Discrepancies
Mini Mental State Examination (MMSE)	30-point questionnaire test for cognitive function	⩾ 27 = normal 19–24 = mild 10–18 = moderate ⩽9 = severe	Stortecky et al.[20] Schoenenberger et al.[19] Kamga et al.[23] Afilalo et al.[18]	2 points for MMSE <21 1 point for MMSE ⩾21 2 points for a MMSE <21 1 point for MMSE ⩾21 a shortened form was incorporated in the ISAR score: MMSE <15/21 = 2 points MMSE <24
Confusion Assessment Method (CAM)	an instrument and diagnostic algorithm for identification of delirium based on four cardinal features of delirium: 1) acute onset and fluctuating course, 2) inattention, 3) disorganized thinking, and 4) altered level of consciousness	presence of features 1, 2, and either 3 or 4	Kamga et al.[23]	Score ⩾4 = delirium
Hospital Anxiety and Depression Scale	questionnaire for anxiety and/or depression	⩾8 out of 21 for either anxiety or depression each item on the questionnaire is scored from 0–3	Afilalo et al.[18]	>11= depressed
Center for Epidemiological Studies-Depression scale (CES-D)	questionnaire for a major depressive episode 10 item = CES-D-10 20 item = CES-D-20	scores form 0–60 ⩾ 16 at risk for clinical depression scores from 0–30 ⩾ 11 at risk	none	
Eye Ball and End of Bed Test	visual appearance and clinical judgment	photograph of the patient (face and full body, with street clothes and mobility aid if present)	Sündermann et al.[21]	2 physicians (one cardiac surgeon and one experienced clinician) estimated the frailty ("overall impression") according the clinical frailty scale form the Canadian Study of Health and Aging
Kansas City Cardiomyopathy Questionnaire (KCCQ)	23 questions addressing 5 health domains	summary score, extent of improvement compared with baseline: moderately large =10 points or very large = 20 points	none	

lbs: pounds; kg: kilogram; g/dl: gram per deciliter; s: seconds; m/s: meter per seconds; cm: centimeter; BMI: body mass index; CES-D: Center for Epidemiological Studies-Depression Scale; kcal: Kilocalories; ADL: Activity of Daily Living; MWT: Meter Walk Test; CAF: comprehensive assessment of frailty; FORECAST: Frailty predicts death One yeaR after Elective Cardiac Surgery Test.

Puri 2016

Frailty

The contribution of mobility, cognition, and nutrition is increasingly being evaluated as a means of identifying potential TAVI candidates unlikely to benefit from the procedure. By assessing the degree of physiological reserve in response to a specific stressor, one can evaluate the degree of frailty.23

Although the precise definition of frailty remains the subject of debate, a recent systematic review identified a consistent associ- ation between frailty and an increased risk of morbidity, mortality, and functional decline post-cardiac surgery.24 The concept of pro- spectively applying an objective frailty assessment in potential TAVI candidates, rather than an 'eyeball' test, was initially proposed in 2012,25 – 27 and has been systematically assessed across several TAVI trials or registries. Although frailty assessed subjectively in a multicentre Canadian TAVI registry was independently associated with late mortality,28 Stortecky *et al.* demonstrated that a multi- dimensional geriatric assessment (assessing cognition,

	nutrition, mobility, activities of daily living, and frailty) across 100 consecutive TAVI candidates significantly improved risk prediction compared with global risk scores.27 Schoenenberger *et al.* prospectively demonstrated an index of frailty to strongly predict post-TAVI func- tional decline when adjusted for both the STS and EuroSCOREs.29 The Katz index was evaluated in 300 consecutive TAVI patients within a single institution.30 This frailty index was associated with early (30-day) and longer-term mortality (median observation per- iod of 537 days), with a threshold Katz Index score of ,6 predicting long-term mortality (*Figure 1C*). Green *et al.* recently reported on a PARTNER substudy evaluating the prognostic value of frailty (as- sessed using a composite of albumin levels, dominant handgrip strength, gait speed, and Katz index) in older TAVI recipients.31 Poor outcome post-TAVI was defined as death, Kansas City Cardio- myopathy Questionnaire overall summary (KCCQ-OS) score ,60 or a decrease of ≥10 points on the KCCQ-OS score from baseline to 1 year. Rates of all-cause mortality and poor post-TAVI outcome were significantly higher in the frail compared with non-frail TAVI re- cipients. A substudy from the US CoreValve trial characterized the health-related quality-of-outcomes status of over 400 patients who underwent trans-femoral TAVI with a self-expanding prosthesis.32 A poor post-TAVI outcome was defined as death, a KCCQ-OS score of ,45, or a decline in KCCQ-OS of ≥10 points at 6-month follow- up. Poor outcomes were reported in 39% of the population, with baseline wheelchair dependency, oxygen-dependency, low serum albumin (among several other factors) independently associating with a poor outcome. Also, a lower distance walked during the 6MWT has been associated with poorer outcomes (*Figure 1D*).33 Al- though these data outline the importance of frailty as a risk factor determining poorer outcomes post-TAVI, there is currently little consensus on the optimal approach to assessing frailty in potential TAVI recipients. FRAILTY-AVR (Frailty Assessment Before Cardiac Surgery and Transcatheter Interventions; NCT 01845207) is an on- going prospective cohort study (*n ¼* 800 patients recruited from 16 sites across Canada, USA, and France) designed to determine which frailty assessment tool is most predictive of mortality or major mor- bidity in elderly patients undergoing SAVR or TAVI. The AHA/ACC guidelines on managing patients with valvular heart disease advocate frailty assessment in addition to global risk scores when assessing procedural risk.34 A simple questionnaire in- cluding six activities of daily life (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) in addition to the mobility/functional status (no walking aid or assistance re- quired or 5-m walk in ,6 s) are used for evaluating frailty. Those patients with at least two frailty indexes are considered to be at moderate-to-high risk for surgical valve intervention, and this could potentially apply to TAVI procedures (*Table 1*)**. Although frailty could sway potential SAVR candidates towards TAVI, predictive models combining clinical factors, and a frailty assessment will likely optimize the selection of TAVI candidates who are most likely to de- rive maximal benefit.**

	ACC 2017
	5.1.3. Functional Assessment 5.1.3.1. Frailty and Disability A comprehensive evaluation includes assessments of frailty, physical function, independence in activities of daily living (ADLs) (e.g., feeding, bathing, dressing, transferring, toileting), and cognitive function (11). An evaluation should start with screening for independence, cognitive function, and slow walking speed (gait speed—3 timed trials over a 5-meter distance). Those with gait speed >0.83m/s and preserved cognition and independence are likely not frail, but those with gait speed <0.5m/sec or with gait speed <0.83m/s with disability or cognitive impairment need further evaluation. Additional assessment can be informed by qualitative rating scales like the Canadian Study of Health and Aging Scale, performance-based assessments like the 'Up and Go' test and chair stands, deficit accumulation summary measures like the Rockwood Frailty Index, or frailty phenotype scales like the Cardiovascular Health Study Frailty Scale or Edmonton Frail Scale (12-18). Nutritional deficiency (body mass index <21 or albumin <3.5g/dL), risk for malnutrition (score ≤11 on Mini Nutritional Assessment), or weight loss (>10lb decline in 1 year) add information on energy intake and consumption (19). The patient can be classified as not frail, pre-frail, or frail with varying severity as an aggregate clinical assessment based on tests performed (20).
Énoncé retenu par le comité:	**2.1.7. L'évaluation du niveau de fragilité devrait être consignée au dossier du patient.** **En présence d'indices de fragilité, l'évaluation devrait être objectivée au moyen de l'administration d'un ou plusieurs test(s) validé(s).** **Si le patient s'avère fragile, un interniste ou un gériatre devrait l'évaluer.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.1 Évaluation préopératoire	INESSS 2012 Processus de sélection des patients Une équipe multidisciplinaire, qui comprend des cardiologues et des chirurgiens cardiaques, doit effectuer l'évaluation de l'état global de chaque patient et décider d'offrir cette intervention après avoir examiné les fonctions cognitives, la fragilité générale et l'état physique ainsi que toutes autres dimensions pertinentes. Puisque la majorité des patients orientés vers cette intervention seront âgés, l'implication active d'un gériatre est tout à fait pertinente.
	ESC/EACTS 2012 Specific validated scores enable the assessment of cognitive and functional capacities which have important prognostic implications in the elderly. The expertise of geriatricians is particularly helpful in this setting.
	CSANZ/ANZSCTS 2015 Typically a Heart Team could include, but is not limited to, the following: Interventional Cardiologist(s) - Cardiothoracic Surgeon(s) - Imaging Cardiologist (CT, TTE, TOE) / Radiologist - TAVI Nurse Case Manager / Co-ordinator - General Cardiologist(s) - Cardiac Anaesthetist - Intensive Care Physician - Geriatrician / General Physician - Vascular Surgeon The use of this type of multi-disciplinary team has been shown to improve outcomes in complex procedures such as TAVI [11,15,23,24]. One of the principle roles of the team is to ensure that patients are adequately evaluated (worked up) and selected for the procedure. This is to ensure all the comorbidities and risks for the patient are evaluated fully.
	VARC-2 2012 The heart team should consist of at least (interventional) cardiologists, cardiovascular surgeons, and imaging specialists, but its composition is dynamic and can also include anesthesiologists, geriatricians, neurologists, etc. This multi-disciplinary team should convene as a group on a regular basis to review and interpret clinical data to arrive at a consensus on the optimal treatment strategy for each patient.
	Puri 2016 A multi-disciplinary Heart Team is fundamental for a global, holistic patient assessment, especially for more specific frailty assessments. The implication of geriatricians is of particular importance in this setting.
Énoncé retenu par le comité:	**2.1.8. Si les aspects évalués précédemment, entre autres la capacité fonctionnelle, les fonctions cognitives et la fragilité sont tels que l'impact d'une éventuelle intervention TAVI sur la qualité de vie du patient est incertain, de l'expertise gériatrique devrait être obtenue.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.2 Processus décisionnel avec le patient	INESSS 2012 Afin de déterminer l'admissibilité du patient, une équipe multidisciplinaire (qui comprend les cardiologues et les chirurgiens cardiaques) doit effectuer une évaluation de l'état global du patient et examiner toutes les dimensions pertinentes. Il faut reconnaître l'importance fondamentale de la perspective du patient, et l'informer de façon exhaustive des risques de mortalité et de morbidité importants associés à l'intervention. La possibilité ou l'exclusion d'une chirurgie valvulaire à coeur ouvert, pratiquée d'urgence en cas de complication grave durant l'implantation valvulaire aortique par cathéter, devrait aussi être discutée avec le patient. Les désirs et les attentes du patient revêtent une importance capitale en ce qui a trait à la décision d'effectuer une intervention. Les objectifs du traitement choisi doivent correspondre à ceux du patient. La notion de « ce qui peut être fait » n'équivaut pas à la notion de « ce qui devrait être fait »
	AHA/ACC 2014 Patient care should be customized to the patient's needs, values, and expectations. The choice of proceeding with surgical versus transcatheter AVR is based on multiple parameters, including the risk of operation, patient frailty, and comorbid conditions. The overall risks versus benefits should then be discussed with the patient and family using a shared decision-making process.
	CCN 2014 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.
	ACC 2017 5.1.1. Shared Decision-Making and the Heart Valve Team The management of patients with severe AS who are being considered for TAVR is best achieved by a multidisciplinary, collaborative Heart Valve Team that includes cardiologists with expertise in valvular heart disease, structural interventional cardiologists, imaging specialists, cardiovascular surgeons, cardiovascular anesthesiologists, and cardiovascular nursing professionals (1) (Table 1). Patient management relies on a shared decision-making approach based on a comprehensive understanding of the risk-benefit ratio of different treatment strategies and integration of patient preferences and values. Shared decision-making involves education of the patient, their family, and the referring physician about treatment alternatives. Patient goals and expectations should be established early in this process in the context of a discussion of life expectancy, anticipated improvement in symptoms or survival, and end-of-life constructs, when appropriate. This enables an exchange about the promise of TAVR as well as the realities of advanced age,

	alternatives to intervention, and palliative care options (Figure 2). 5.1.5. Integrated Benefit-Risk of TAVR and Shared Decision-Making Based on the key elements of pre-TAVR evaluation, the final treatment decision should be individualized based on clinical and imaging evaluation, risk category, patient goals and expectations, and futility considerations as recommended in the updated AHA/ACC Guideline for Management of Patients with Valvular Heart Disease (see Section 3.2.4 Aortic Stenosis: Choice of Intervention). Heart Valve Team evaluation may conclude that SAVR is the best option for an individual patient if, for example, surgical risk is low, the durability of a mechanical or other tissue valve is preferred in a younger patient, or concurrent surgical procedures such as aortic root replacement or coronary bypass grafting are needed. Even when severe symptomatic AS is present, TAVR is considered futile when the expected benefit from TAVR is less than the expected risk; in these patients, palliative care may be the best option in terms of both quality and length of life. In patients who meet guideline based criteria for TAVR and for whom pre-TAVR evaluation indicates the benefit of TAVR is greater than risk, discussion with the patient and family should again review the likelihood of symptom relief or improved survival, discuss possible complications and the expected recovery process, and ensure that patient goals and expectations are aligned with the possible procedural outcomes.
Énoncé retenu par le comité:	**2.2.1. Le but et les attentes du patient et de ses proches devraient être établis de façon précoce, transparente et dans un niveau de langage approprié dans le cadre d'une discussion portant sur les éléments suivants : objectifs de soins, risques et conséquences d'une intervention TAVI, amélioration anticipée des symptômes, de l'espérance de vie, ainsi que sur les autres options de traitement, y compris l'absence d'intervention.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.3 Sélection des patients	INESSS 2012 Il doit exister chez ces patients une probabilité raisonnable que leur qualité de vie (p. ex., liée à la capacité fonctionnelle, à l'autonomie, aux activités de la vie quotidienne/domestique) s'améliore de façon significative grâce à l'intervention et qu'elle se maintienne pendant au moins 1 an.
	VARC-2 2012 In addition to the specific risk factors that can prohibit patients from undergoing TAVI or surgical aortic valve replacement (SAVR) (Table 1), the operative risk assessment is also important to identify patients who are likely not to benefit from either TAVI or SAVR (the so-called ''futility'' category of highrisk patients). An expected improvement in the quality of life (QOL) may further be necessary to identify treatment responders versus non-responders.
	AHA/ACC 2014 it is appropriate to defer any type of intervention in patients who will not benefit in terms of symptoms or improved life span from the procedure. This group of patients in whom surgical or transcatheter intervention for severe VHD is futile are those with 1) a life expectancy of <1 year, even with a successful procedure, and 2) those who have a chance of "survival with benefit" of <25% at 2 years. Survival with benefit means survival with improvement by at least 1 New York Heart Association (NYHA) or Canadian Cardiovascular Society class in heart failure (HF) or angina symptoms, improvement in quality of life, or improvement in life expectancy. Those patients with severe frailty may fall into this category.
	Puri 2016 Therapeutic futility is a generic term corresponding to a lack of medical efficacy. Although there is currently no uniform definition,7 futility from a TAVI perspective is usually defined by the combination of death and/or absence of functional improvement during short-term follow-up post-procedure (6 months to 1 year).
	ACC 2017 In addition to frailty and disability, assessment of futility is an important consideration in therapeutic decision-making (4). It is appropriate to avoid intervention in patients who will not benefit in terms of symptoms or improved life span from the procedure. This group of patients in whom SAVR or TAVR for severe AS is considered futile are those with 1) a life expectancy <1 year, despite a successful procedure, and 2) those who have a chance of "survival with benefit" <25% at 2 years. "Survival with benefit" implies survival with improvement by at least 1 New York Heart Association class in heart failure or by at least 1 Canadian Cardiovascular Society class angina symptoms, improvement in quality of life, or improvement in life expectancy (25). If a procedure is considered futile and not recommended, it is important that care plans are put into place to prevent a feeling of abandonment by the patient, family, or caregivers. Input from palliative care specialists is particularly helpful in such situations.

Énoncé retenu par le comité:	**2.3.1. Il convient d'éviter de procéder à l'intervention TAVI chez les patients qui ne sont pas susceptibles de bénéficier d'une amélioration de la qualité et de la durée de vie. Ces patients sont ceux qui, en dépit d'une intervention réussie:** • **ont une espérance de vie inférieure à un an;** • **ont une faible probabilité d'amélioration de la qualité et/ou de durée de vie anticipée.**

2. Normes relatives à l'évaluation, au processus décisionnel et à la sélection des patients	
2.3 Sélection des patients	INESSS 2012 Une équipe multidisciplinaire, qui comprend des cardiologues et des chirurgiens cardiaques, doit effectuer l'évaluation de l'état global de chaque patient et décider d'offrir cette intervention après avoir examiné les fonctions cognitives, la fragilité générale et l'état physique ainsi que toutes autres dimensions pertinentes.
	VARC-2 2012 Individualized life expectancy assumptions should be incorporated by the heart team in the clinical decision-making process as a central factor in weighing the risk–benefit ratio. The most important role of the heart team is to provide customized management decisions for common and unusual clinical scenarios in terms of patient selection, procedural performance, and complication management.
	AHA/ACC 2014 The Heart Valve Team should optimize patient selection for available procedures through a comprehensive understanding of the risk–benefit ratio of different treatment strategies.
	CSANZ/ANZSCTS 2015 One of the principle roles of the team is to ensure that patients are adequately evaluated (worked up) and selected for the procedure. This is to ensure all the comorbidities and risks for the patient are evaluated fully and the best treatment option for the patient (medical therapy, traditional surgery or transcatheter valve therapy) is considered. Such decisions should be considered in a formal case conference involving the members of the Heart Team. Pro-formas are useful to ensure all information is presented succinctly; minutes of the meeting, including a synopsis of the discussion and the eventual decision, should be recorded.
	ACC 2017 Patient management relies on a shared decision-making approach based on a comprehensive understanding of the risk-benefit ratio of different treatment strategies and integration of patient preferences and values
Énoncé retenu par le comité:	**2.3.2. Sur la base de l'ensemble des informations recueillies, l'équipe multidisciplinaire TAVI :** • **devrait évaluer le rapport risque / bénéfice de chaque option de traitement;** • **documenter le risque opératoire (faible, modéré, élevé, excessif);** • **proposer la modalité de traitement retenue parmi les trois suivantes :** o **remplacement valvulaire aortique (RVA) chirurgical;** o **implantation valvulaire aortique par cathéter;** o **traitement médical.**

3. Normes relatives à la gestion post-opératoire et au suivi des patients	
	CCN 2014 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. 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.

3.1. Gestion post opératoire et congé

Lauck 2016

Table 2. Vancouver Transcatheter Aortic Valve Replacement Clinical Pathway Discharge Criteria

Monitoring
Completion and review of postprocedure transthoracic echocardiogram to confirm acceptable bioprosthetic hemodynamics with the absence of delayed complications.
Absence of persistent intraventricular conduction delay.
Absence of vascular access site complications.
Absence of laboratory contraindications. If Hgb <100 g/L and eGFR <30 mL/min, obtain and review outpatient bloodwork 2 and 4 d after discharge.
Facilitated Reconditioning
Return to baseline mobilization.
Absence of elimination issues (eg, urinary retention).
Communication
Multidisciplinary agreement of safety of discharge.
Confirmation of discharge plan with patient/family.
Confirmation of availability of social support during the initial 48 h after discharge.
Completion of verbal discharge teaching and confirmation of patients/ family's understanding of the discharge guidelines and provision of written discharge education resources and prescription of medications.

eGFR indicates estimated glomerular filtration rate; and Hgb, hemoglobin.

ACC 2017

5.4.1. Immediate Postprocedure Management

After the TAVR procedure, patients should be managed in accordance with institutional protocols for monitoring and recovery after sedation or anesthesia.

5.4.1.1. Waking from Sedation

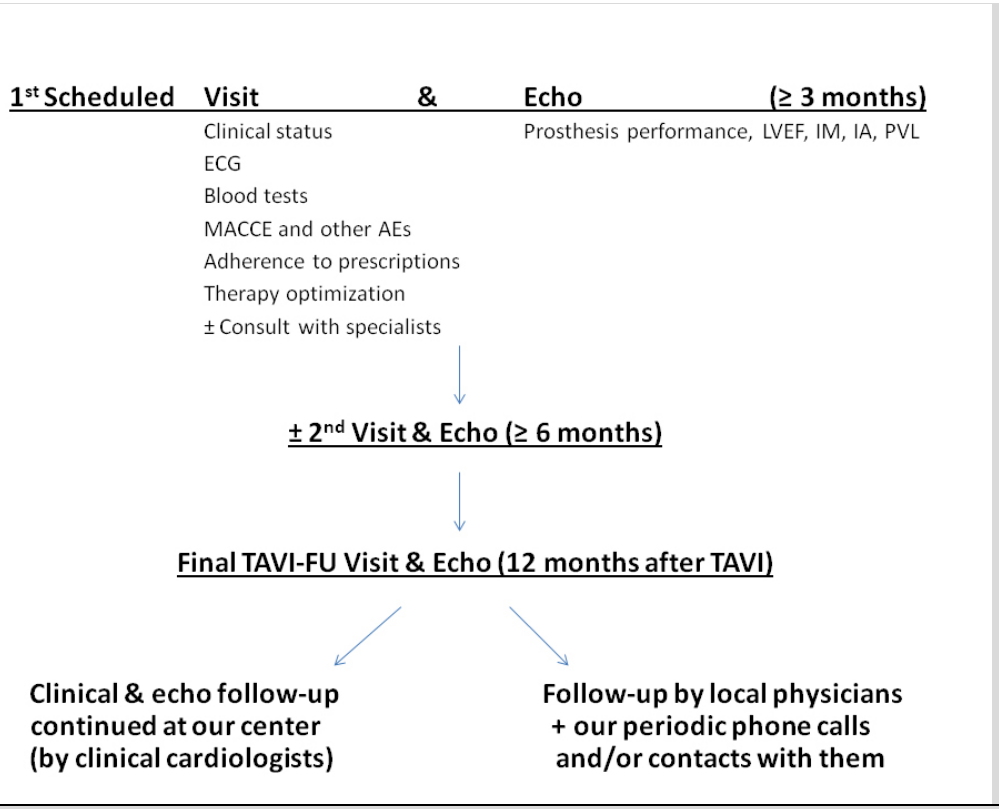
When general anesthesia is used, early extubation is encouraged, as for any general anesthesia procedure.

5.4.1.2. Postprocedure Monitoring

With both general anesthesia and conscious sedation, hospital protocols are followed for monitoring mental status, telemetry, vital signs, volume status, and postprocedure blood testing. In addition, the access site should be monitored carefully to ensure adequate hemostasis with normal distal blood flow. Monitoring the access site also allows early detection and intervention for bleeding, hematoma or pseudoaneurysm formation.

	5.4.1.3. Pain Management Appropriate pain management, continued mental status monitoring, and early mobilization are especially important post-TAVR as patients often are elderly with a high burden of comorbidities. Pre-operative medications should be reviewed, with all that remain appropriate restarted promptly. 5.4.1.4. Early Mobilization A structured discharge plan should be initiated prior to the procedure and should include physical and occupational therapy assessment to determine the appropriate disposition after hospitalization and scheduling of postdischarge outpatient medical care. 5.4.1.5. Discharge Planning Early discharge (within 72 hours) does not increase the risk of 30-day mortality, bleeding, pacer implantation or rehospitalization in selected patients undergoing transfemoral TAVR (53).
Énoncé retenu par le comité:	**3.1.1. Chaque programme devrait avoir un protocole écrit relatif à la gestion postopératoire des patients ainsi qu'à l'attribution du congé et à la planification du retour dans la collectivité.**

3. Normes relatives à la gestion post-opératoire et au suivi des patients	
3.2. Suivi des patients	Aranzulla 2016 In our structure, the FU of TAVI patients is organized and conducted in a specialized clinic of the Cardiovascular Division. Clinical visits are performed by the interventional cardiologists with the aid of a cardiologist experienced in TAVI imaging, mainly echo, and also involved in the procedure. During every visit clinical status is assessed, as well as compliance to therapy. The latest blood exams of the patient are evaluated and an ECG and echocardiogram are performed. Every complex patient is managed in tight collaboration with cardiac surgeons, nephrologists, immunologists, oncologists, geriatricians and any other specialists (including the psychologist) who may be needed for the solution of the specific comorbidities. The FU is organized by planning the timing of the first visit (varying from 30 days to three months according to the clinical status) at discharge. Every patient is followed up for 12 months, then with periodic visits. After this period, the patient is addressed, according to the patient's preference, either to our clinical cardiologists or to the referral cardiologist/cardiology center and to the GP. Those patients who do not adhere to out-patient visits are followed up by phone calls and by direct contact with the referring physicians.



ACC 2017

The Heart Valve Team (or interventional/surgical team) is responsible for care for the first 30 days because procedural complications are most likely in this time interval. After 30 days, there should be a formal transfer of care from the Heart Valve Team back to the referring primary cardiologist. In stable patients with no complications and few comorbidities, the primary cardiologist should see the patient at 6 months and then annually, and more frequently as needed for complications or concurrent medical conditions. In addition, the primary care provider or geriatrician should be involved before and after the TAVR procedure and should assume primary responsibility for patient care starting at 30 days, with the first primary care provider appointment scheduled no later than 3 months after the procedure. The primary care provider and cardiologist should communicate frequently to ensure coordination of care, with clear patient instructions on when and how to contact the care team. Education and active involvement of the patient in managing their condition is important. Periodic reassessment and discussion of the goal of care (symptoms or survival) and patient preferences are helpful in guiding care and ensuring patient satisfaction.

Énoncé retenu par le comité:	**3.2.1. Sans égard au suivi effectué par le médecin traitant, l'équipe multidisciplinaire TAVI devrait en assumer la responsabilité pendant au moins les 30 premiers jours. Au terme de cette période, un transfert formel devrait être effectué au médecin traitant qui assurera le suivi ultérieur.** **Celui-ci devrait recevoir toute l'information pertinente en ce qui a trait à l'épisode de soins.** **3.2.2. L'équipe multidisciplinaire TAVI devrait toutefois contacter les patients à 1 an et s'enquérir de leur situation et consigner cette information permettant ainsi au comité interdisciplinaire d'amélioration continue de consigner les résultats cliniques spécifiques du programme sur une base annuelle et d'y apporter les ajustements nécessaires au besoin.** **3.2.3. Le patient stable qui n'a pas eu de complications et qui présente peu de comorbidités devrait être évalué dans les 6 mois suivant son intervention par le médecin référent et ensuite, tous les ans, ou plus fréquemment, au besoin, en cas de complications ou de conditions médicales concomitantes.** **Dans l'éventualité où un mauvais fonctionnement de la valve est suspecté, le patient devrait être référé de nouveau à l'équipe multidisciplinaire TAVI.**

CLASSES DE RECOMMANDATIONS ET NIVEAUX D'ÉVIDENCE

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

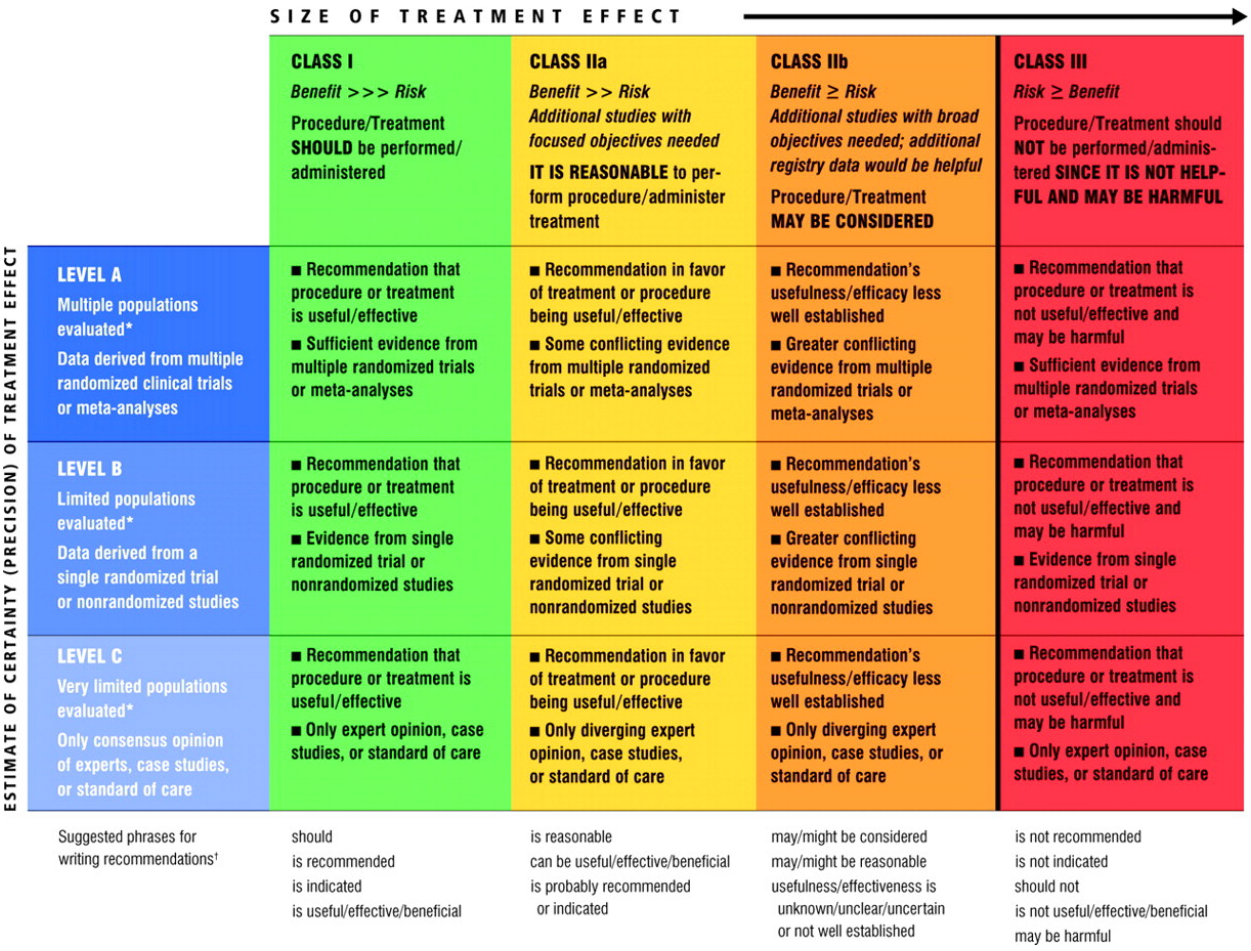
Table 1 Classes of recommendations

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	*Weight of evidence/opinion is in favour of usefulness/efficacy.*	Should be considered
Class IIb	*Usefulness/efficacy is less well established by evidence/opinion.*	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Table 2 Levels of evidence

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/ or small studies, retrospective studies, registries.

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



SIZE OF TREATMENT EFFECT →

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *Risk ≥ Benefit* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations†	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

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