



# Cardiac Care Network

Transcatheter Aortic Valve Intervention Registry

(Ver 1.1)

Last Updated: April 25<sup>th</sup>, 2010

Data + Operational definitions



PART 1: BASELINE CHARACTERISTICS

EuroSCORE required fields are highlighted in bold orange – see <http://www.euroscore.org/calc.html>

Code	Data field	Options	Operationalized definition
<b>Patient screening – Demographics</b>			
	First Name	User input field	•
	Last Name	User input field	•
	<b>Date of birth</b>	<b>User input field</b>	• <b>Age at time of referral</b>
	<b>Gender</b>	<b>Male</b> <b>Female</b>	
	Home Phone	User input field	
	Other Phone	User input field	
	Enrolment	Canadian Special Access Study	
	Living status	Home independent	<ul style="list-style-type: none"> <li>• Does not require any home supports</li> <li>• Able to meet needs for activities of daily living (ADL) and instrumental activities of daily living (IADL)</li> </ul>
		Home dependent	<ul style="list-style-type: none"> <li>• Requires home supports for ADLs and/or IADLs</li> </ul>
		Assisted living	<ul style="list-style-type: none"> <li>• Lives in care facility that provides intermittent assistance for ADLs and/or IADLs</li> </ul>
		Residential care	<ul style="list-style-type: none"> <li>• Lives in care facility that provides continuous assistance for ADLs and/or IADLs</li> </ul>
		Acute care in-patient	<ul style="list-style-type: none"> <li>• Admitted in acute care setting at time of referral</li> </ul>
	Hospital	University Health Network	<ul style="list-style-type: none"> <li>• Central referring centre that receives referral</li> </ul>



		University of Ottawa Health Institute Hamilton Health Sciences Centre London Health Sciences Centre St. Michael's Hospital Sunnybrook Health Sciences Centre	<ul style="list-style-type: none"> <li>Hospital affiliation of cardiologist or cardiac surgeon who receives initial referral</li> </ul>
	Referring physician	User input field	<ul style="list-style-type: none"> <li>Primary care physician or specialist who refers patient to TAVI centre or physician</li> </ul>
	Accepting physician	User input field	<ul style="list-style-type: none"> <li>T-AVI accepting physician</li> </ul>
	Other referring physician	User input field	<ul style="list-style-type: none"> <li>Additional physician involved in referral process</li> </ul>
	Wait time #1 Date of Referral	Date	<ul style="list-style-type: none"> <li>Earliest date referral is received by TAVI centre or physician</li> </ul>
	Health Card Number	User input field	<ul style="list-style-type: none"> <li></li> </ul>
	Backdated entry	No Yes	<ul style="list-style-type: none"> <li></li> </ul>
<b>Patient screening – Cardiac status at time of referral</b>			
<b>Myocardial ischemia</b>			
	Past Myocardial infarction	No Yes	<ul style="list-style-type: none"> <li>No previous history of MI</li> <li>Previous MI</li> </ul>
	<b>Recent MI Interval</b>	<b>&lt; 90 days (euroSCORE)</b> <b>≥ 90 days</b>	<ul style="list-style-type: none"> <li>Date of last MI event</li> </ul>
	<b>Post infarct septal rupture</b>	<b>No</b> <b>Yes</b>	<ul style="list-style-type: none"> <li><b>No previous history of MI-related septal rupture</b></li> <li><b>Past history of of MI-related septal rupture</b></li> </ul>
	Angina pectoris	No Yes	<ul style="list-style-type: none"> <li>No:                             <ul style="list-style-type: none"> <li>No current experience and/or treatment of angina</li> <li>No use of antianginal medication (e.g. nitrates)</li> </ul> </li> </ul>



			<ul style="list-style-type: none"> <li>• Yes: Current experience and/or treatment of angina</li> </ul>
	Angina type	Stable Unstable	<ul style="list-style-type: none"> <li>• Stable: occurs with activity/stress and relieved with rest/medications</li> <li>• Unstable: occurs with or without activity/stress and does not respond to rest/medications</li> </ul>
	Angina Severity (CCS)	I II III IV a IV b IV c IV d	<ul style="list-style-type: none"> <li>• Class I: Ordinary physical activity such as walking, climbing stairs does not cause angina. Angina (occurs) with strenuous, rapid or prolonged exertion at work or recreation</li> <li>• Class II: Slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions</li> <li>• Class III: Marked limitations of ordinary physical activity. Angina occurs on walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.</li> <li>• Class IV: Inability to carry on any physical activity without discomfort - anginal symptoms may be present at rest.             <ul style="list-style-type: none"> <li>• IVa: Patient admitted to hospital and becomes relatively asymptomatic with aggressive medical therapy</li> <li>• IVb: Patient admitted to hospital and continues to experience angina on maximal medical therapy and cannot be safely discharged home, but does not require IV nitroglycerin.</li> <li>• IVc: Patient admitted to hospital and maximal medical therapy, including IV nitroglycerin, fails to control symptoms or there is hemodynamic instability.</li> <li>• IVd: Cardiogenic shock</li> </ul> </li> </ul>
	<b>Heart Failure</b>		
	CHF	No Yes	<ul style="list-style-type: none"> <li>• Absence of diagnosis and symptoms of heart failure</li> <li>• Diagnosis, symptoms and treatment of heart failure</li> </ul>



	Functional class NYHA	N/A, Class I-IV	<ul style="list-style-type: none"> <li>• N/A – Absence of heart failure and asymptomatic</li> <li>• Class I – Mild: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</li> <li>• Class II - Mild: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</li> <li>• Class III - Moderate: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</li> <li>• Class IV – Severe: Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</li> </ul>
	LV function	LVEF > 50% LVEF 30-50% LVEF < 30%	<ul style="list-style-type: none"> <li>• Assessment of LV function</li> </ul>
	NT-ProBNP	ng/ml	<ul style="list-style-type: none"> <li>• NT-ProBNP serum level</li> </ul>
	Active endocarditis	No Yes	<ul style="list-style-type: none"> <li>• No active endocarditis present</li> <li>• Patient still on antibiotic treatment for endocarditis at time of referral</li> </ul>
<b>Arrhythmia</b>			
	Baseline cardiac rhythm	Sinus rhythm (SR) AF/AFL Paced	<ul style="list-style-type: none"> <li>• Dominant rhythm – may experience other arrhythmia intermittently</li> <li>• Sinus rhythm – with or without occasional AF or paced beats</li> <li>• Atrial fibrillation or flutter: permanent or persistent</li> <li>• Paced: Permanently paced rhythm</li> </ul>
	Arrhythmia history	No	<ul style="list-style-type: none"> <li>• No previous history of symptomatic arrhythmias</li> </ul>
		Yes If Yes, selection Checkbox AF/AFL Symptomatic heart block	<ul style="list-style-type: none"> <li>• Previous history of intermittent or permanent arrhythmia</li> <li>• History of paroxysmal, persistent or permanent atrial fibrillation or flutter</li> <li>• History of symptomatic heart block that required treatment (e.g.</li> </ul>



		Sust VT or VF	<p>pacemaker)</p> <ul style="list-style-type: none"> <li>History of ventricular tachycardia or fibrillation that required treatment (e.g. amiodarone, ICD)</li> </ul>
Cardiac device	No		<ul style="list-style-type: none"> <li>No previous implant of cardiac arrhythmia device</li> </ul>
	Yes: Pacemaker Yes: ICD		<ul style="list-style-type: none"> <li>Patient has a permanent pacemaker</li> <li>Patient has an implantable cardioverter-defibrillator</li> </ul>
<b>Patient screening – Risk factors/comorbid conditions at time of referral</b>			
Weight		Kg/lbs	<ul style="list-style-type: none"> <li>Patient's weight at time of referral</li> <li>Do not use target weight set for heart failure management</li> </ul>
Height		cm /in	
Smoking history		Non-smoker Remote Quit < 6 months ago Current	<ul style="list-style-type: none"> <li>Never or rarely smoked</li> <li>Quit more than 6 months ago</li> <li>Quit less than 6 months ago</li> <li>Current smoker</li> </ul>
Diabetes	No		<ul style="list-style-type: none"> <li>No history of treated or untreated diabetes</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Past or current history of diagnosed and/or treated diabetes including diet-controlled, oral hypoglycemic or insulin</li> </ul>
Dyslipidemia	No		<ul style="list-style-type: none"> <li>No history of diagnosed and/or treated abnormal lipid profile</li> <li>Not taking lipid-lowering medication</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>History of diagnosed and/or treated abnormal lipid profile</li> <li>May or may not be taking lipid lowering medication</li> </ul>
Hypertension	No		<ul style="list-style-type: none"> <li>No history of diagnosed and/or treated hypertension</li> <li>Not taking antihypertensive medication</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>History of diagnosed and/or treated hypertension</li> <li>May or may not be taking antihypertensive medication</li> </ul>
Extracardiac arteriopathy		No	<ul style="list-style-type: none"> <li>No history of claudication, carotid occlusion or &gt;50% stenosis, previous or planned intervention on the abdominal aorta, limb arteries or carotids</li> </ul>



		Yes	<ul style="list-style-type: none"> <li>History of one or more of claudication, carotid occlusion or &gt;50% stenosis, previous or planned intervention on the abdominal aorta, limb arteries or carotids</li> </ul>
	Neurological dysfunction	No	<ul style="list-style-type: none"> <li>No history of neurological disease severely affecting ambulation or day-to-day functioning</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>History of neurological disease severely affecting ambulation or day-to-day functioning</li> </ul>
	Cerebrovascular disease	No	<ul style="list-style-type: none"> <li></li> </ul>
		Yes	<ul style="list-style-type: none"> <li></li> </ul>
	Cerebrovascular events	No Yes If Yes, TIA,RIND, CVA selection	<ul style="list-style-type: none"> <li>History of transient ischemic attack with resolution &lt; 24 hours</li> <li>History of reversible ischemic neurological deficit with resolution within 24 to 72 hours</li> <li>History of cerebrovascular attack with effects extending beyond 72 hours</li> </ul>
	CVA Time (event interval)	< 14 days ≥ 14 days	<ul style="list-style-type: none"> <li>Time since most recent cerebrovascular event, including TIA, RAND and CVA</li> <li>Less than 14 days ago</li> <li>14 days and longer</li> </ul>
	Carotid disease	No Yes if Yes, Carotid disease details	<ul style="list-style-type: none"> <li>No history of diagnosed or treated carotid disease</li> <li>History of diagnosed carotid stenosis</li> </ul>
		Carotid disease details <ul style="list-style-type: none"> <li>Unilateral</li> <li>Bilateral</li> <li>Unknown</li> </ul>	<ul style="list-style-type: none"> <li>Carotid occlusion or &gt; 50% stenosisDiagnostic anatomical findings (e.g. Doppler or angiography)</li> </ul>
		Asymptomatic Symptomatic	<ul style="list-style-type: none"> <li>No symptoms associated with carotid disease</li> <li>Symptomatic due to carotid disease</li> </ul>



		Previous CEA No Previous CEA Yes	<ul style="list-style-type: none"> <li>No previous history of carotid endarterectomy</li> <li>History of carotid endarterectomy</li> </ul>
	<b>Renal function</b>		
	<b>Creatinine</b>	< 120 µmol/L 120 – 200 µmol/L ≥ 200 µmol/L	<ul style="list-style-type: none"> <li>Baseline/pre-operative serum creatinine</li> </ul>
	eGFR	> 50 mls/min ≤ 50 mls/min	<ul style="list-style-type: none"> <li>Baseline/pre-operative estimated glomerular filtration rate</li> </ul>
	Dialysis	No Yes	<ul style="list-style-type: none"> <li>No history of peritoneal or hemodialysis</li> <li>Presently on peritoneal or hemodialysis</li> </ul>
	Hemoglobin	If male: > 140 g/L 90 – 140 g/L < 90 g/L If female: > 120 g/L 80 – 120 g/L < 80 g/L	<ul style="list-style-type: none"> <li>Baseline/pre-operative serum hemoglobin</li> </ul>
	PVD	No Yes	<ul style="list-style-type: none"> <li>No history of diagnosed and/or treated peripheral vascular disease</li> <li>History of diagnosed and/or treated peripheral vascular disease</li> </ul>
	<b>Pulmonary hypertension</b>	No	<ul style="list-style-type: none"> <li>No history of diagnosed and/or treated pulmonary hypertension</li> <li>Systolic pulmonary artery pressure &lt; 60 mmHg</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>History of diagnosed and/or treated pulmonary hypertension</li> <li>Systolic pulmonary artery pressure &gt; 60 mmHg</li> </ul>
	<b>COPD/COLD</b>	No	<ul style="list-style-type: none"> <li>No history of diagnosed and/or treated chronic obstructive pulmonary or lung disease</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>History of diagnosed and/or treated chronic obstructive pulmonary or lung disease with long term use of bronchodilators or steroids</li> </ul>



		If Yes: Pulmonary function testing Normal Abnormal	<ul style="list-style-type: none"> <li>Results of pulmonary function test</li> </ul>
	COPD/COLD severity	Mild Moderate Severe	<ul style="list-style-type: none"> <li>Severity of effect of lung disease on dyspneic symptoms, activity level and quality of life</li> </ul>
<b>Patient screening – Previous cardiac procedures</b>			
	Previous cardiac procedure	No	<ul style="list-style-type: none"> <li>No previous cardiac surgical or interventional cardiology procedure</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>History of cardiac surgery, cardiac device implant and/or interventional cardiology procedure</li> </ul>
	Previous cardiac surgery (CS)	No	<ul style="list-style-type: none"> <li>No previous cardiac surgery, including coronary artery bypass graft (CABG), surgical valve replacement, pacemaker or ICD implantation</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>History of CABG, valve surgery and/or pacemaker/ICD</li> </ul>
		<i>If Yes to cardiac surgery:</i> Previous cardiac surgery interval < 1 month 1-12 months > 12 months	<ul style="list-style-type: none"> <li>Time interval since most recent cardiac surgery</li> </ul>
		CABG Valve surgery Other - Specify	<ul style="list-style-type: none"> <li>Previous CABG</li> <li>Previous valve surgery</li> </ul>
	Aortic valve	No	<ul style="list-style-type: none"> <li>No history of aortic valve surgery</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Select one or more of aortic valve surgeries</li> </ul>
		<i>If Yes to aortic valve surgery, select:</i> 1. Aortic valve replacement 2. Aortic valve repair/reconstruction 3. Aortic valve other surgery	<ul style="list-style-type: none"> <li>AVR with mechanical or bioprosthesis</li> <li>AoV repair with preservation of native annulus</li> </ul>



		<ul style="list-style-type: none"> <li>• Aortic valve other surgery description</li> </ul>	<ul style="list-style-type: none"> <li>• Provide description of AoV alternative surgery</li> </ul>
	Mitral valve	No	<ul style="list-style-type: none"> <li>• No history of mitral valve surgery</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Select one or more of mitral valve surgeries</li> </ul>
		<p><i>If Yes to mitral valve surgery, select</i></p> <ol style="list-style-type: none"> <li>1. Mitral valve annuloplasty</li> <li>2. Mitral valve replacement</li> <li>3. Mitral valve repair/reconstruction with annuloplasty</li> <li>4. Mitral valve repair/reconstruction without annuloplasty</li> <li>5. Mitral valve other surgery</li> </ol> <ul style="list-style-type: none"> <li>• Mitral valve other surgery description</li> </ul>	<ul style="list-style-type: none"> <li>• Surgical placement of MV annuloplasty ring</li> <li>• MV replacement with mechanical or bioprosthesis</li> <li>• MV repair with preservation of native annulus and surgical placement of MV annuloplasty ring</li> <li>• MV repair with preservation of native annulus without surgical placement of MV annuloplasty ring</li> <li>• E.g. Alfieri edge-to-edge repair,</li> <li>• Provide description of MV alternative surgery</li> </ul>
	Tricuspid valve	<p><i>If Yes to tricuspid valve surgery, select:</i></p> <ol style="list-style-type: none"> <li>1. Tricuspid valve annuloplasty</li> <li>2. Tricuspid valve replacement</li> <li>3. Tricuspid valve repair/reconstruction with annuloplasty</li> <li>4. Tricuspid valve repair/reconstruction without annuloplasty</li> <li>5. Tricuspid valve other surgery</li> </ol> <ul style="list-style-type: none"> <li>• Mitral valve other surgery</li> </ul>	<ul style="list-style-type: none"> <li>• Surgical placement of TV annuloplasty ring</li> <li>• TV replacement with mechanical or bioprosthesis</li> <li>• TV repair with preservation of native annulus and surgical placement of MV annuloplasty ring</li> <li>• TV repair with preservation of native annulus without surgical placement of MV annuloplasty ring</li> <li>• Provide description of TV alternative surgery</li> </ul>



		description	
	Pulmonic valve	<p><i>If Yes to pulmonic valve surgery, select:</i></p> <ol style="list-style-type: none"> <li>1. Pulmonic valve replacement</li> <li>2. Pulmonic valve repair/reconstruction</li> <li>3. Pulmonic valve other surgery                             <ul style="list-style-type: none"> <li>- Pulmonic valve other surgery description</li> </ul> </li> </ol>	<ul style="list-style-type: none"> <li>• PVR with mechanical or bioprosthesis</li> <li>• PV repair with preservation of native annulus</li> <li>• Provide description of PV alternative surgery</li> </ul>
	<b>Surgery on thoracic aorta</b>	<p>No</p> <p>Yes</p>	<ul style="list-style-type: none"> <li>• No previous history of thoracic aortic repair</li> <li>• Previous history of thoracic aortic repair</li> </ul>
	Previous other cardiac surgery	<p><i>If Yes to previous other cardiac surgery, select:</i></p>	<ul style="list-style-type: none"> <li>• Record additional cardiac surgeries that are neither CABG nor valve surgery</li> </ul>
		Aortic aneurysm repair	<ul style="list-style-type: none"> <li>• Surgical aortic aneurysm repair</li> </ul>
		ASD repair	<ul style="list-style-type: none"> <li>• Surgical atrial septal defect repair</li> </ul>
		VSD repair	<ul style="list-style-type: none"> <li>• Surgical ventricular septal defect repair</li> </ul>
		Other cardiac surgery	
		Other cardiac surgery description	<ul style="list-style-type: none"> <li>• Provide description of cardiac surgery</li> </ul>
	Previous interventional cardiology procedure	<p><i>If Yes to previous interventional cardiology procedure:</i></p> <p>Previous int card proc interval</p> <p>&lt; 1 month</p> <p>1-12 months</p> <p>&gt; 12 months</p>	<ul style="list-style-type: none"> <li>• Time interval since most recent interventional cardiology procedure</li> </ul>
		<p><i>If Yes to previous interventional cardiology procedure, select valve procedures</i></p>	
		Previous PCI	<ul style="list-style-type: none"> <li>• Previous percutaneous coronary intervention (angioplasty +/- stent)</li> </ul>
		Percutaneous valve procedure	<ul style="list-style-type: none"> <li>• Previous percutaneous valve procedure, including valvuloplasty, valve</li> </ul>



			repair
			<ul style="list-style-type: none"> <li>No previous percutaneous valve procedure</li> </ul>
		If Yes to percutaneous valve procedure, select: Aortic Mitral Tricuspid Pulmonic	<ul style="list-style-type: none"> <li>Select valve(s) that have been treated percutaneously to date</li> </ul>
		Other percutaneous procedures	<ul style="list-style-type: none"> <li>Record additional percutaneous cardiology procedures (including intra-cardiac closure device)</li> </ul>
		Other percutaneous procedures description	
	<b>Previous arrhythmia-related procedure</b>	No Yes If Yes, Arrhythmia proc interval < 1 month 1-12 months > 12 months Arrhythmia Procedure selection <ul style="list-style-type: none"> <li>EPS/Ablation</li> <li>Pacemaker implant</li> <li>ICD implant</li> <li>Other (Other Description)</li> </ul>	<ul style="list-style-type: none"> <li></li> </ul>
	<b>Other Procedure</b>	No Yes if yes provide description of procedure	<ul style="list-style-type: none"> <li></li> </ul>
<b>Patient screening – Pre-admission medication profile</b>			
	Aspirin	Yes No	<ul style="list-style-type: none"> <li>Regular aspirin, any dose</li> </ul>
	Anti-platelet	Yes	<ul style="list-style-type: none"> <li>E.g. clopidogrel ,IIB or IIIa Ihibitor and Other provide description</li> </ul>



		No If Yes, check off clopidogrel ,Iib/IIIa Ihibitor and Other provide description	
	Anticoagulant	Yes No If Yes, please check off Walfarin, LMWH, Heparin and other (provide description)	<ul style="list-style-type: none"> <li>Includes oral, subcutaneous or intravenous agents</li> </ul>
	Beta blocker	Yes No	
	ACE-I	Yes No	
	ARB	Yes No	
	Calcium channel blocker (CCB)	Yes No	
	Diuretic	Yes No	<ul style="list-style-type: none"> <li>Includes oral and intravenous agents</li> </ul>
	Digoxin	Yes No	
	Nitrates	Yes No	<ul style="list-style-type: none"> <li>Includes sublingual, transdermal, oral, intravenous agents</li> </ul>
	Cholesterol-lowering statin	Yes No	
	Amiodarone	Yes No	<ul style="list-style-type: none"> <li>Includes oral and intravenous agents</li> </ul>
	Other cardiac	Yes	<ul style="list-style-type: none"> <li>List other cardiac medications</li> </ul>



	medication	No If Yes provide description	
<b>Patient screening – Angiography details</b>			
	Cath date	Date	<ul style="list-style-type: none"> <li>• Date of TAVI screening diagnostic angiography – e.g. femoral angios +/- pre-procedure coronary angios</li> <li>• Date format: DD/MMM (3 first letters)/YY</li> </ul>
	LH (Left Heart) Cath done	Yes No	
	If LHC is Yes: LVEDP	mmHg	<ul style="list-style-type: none"> <li>• Left ventricular end-diastolic pressure obtained by echo or cardiac</li> </ul>
	LV angio done	Yes No	
	If LV angio done is Yes => MR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	
	If LV angio done is Yes => LVEF	%	
	Root Angio Done	Yes No	
	If Root Angio Done is Yes => AR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	
<b>AoV evaluation</b>			
	AoV Area	cm2	Aortic valve size calculated by cardiac catheterization
	Mean Transvalvular gradient	mmHg	<ul style="list-style-type: none"> <li>• Mean LV/Ao transvalvular gradient obtained by catheterization</li> <li>• <i>Need consistent language with echo form</i></li> </ul>



	AoV Calcification	None/Mild Moderate Severe	•
	AoV annulus size	mm	•
	RHC (Right Heart Cath) done	Yes No	• Mitral valve regurgitation grading by catheterization <i>Should we replace grading with Mild, Moderate, Moderate to severe, Severe?</i>
	IF RHC done = Yes then SPAP MPAP CO	mmHg mmHg L/min	•
	Coronary Angiogram Done	No Yes	•
	CAD (Coronary artery disease)	No Yes	• Coronary artery disease diagnosed on angiography
	Number of disease vessels		•
	Femoral angiogram	No Yes	•
	Minimal femoral diameter	If Yes to Femoral angiogram: mm	• Angiographic measurement of femoral artery at most narrow segment
	Femoral calcification	If Yes to Femoral angiogram: None Mild Moderate Severe	•
<b>Patient screening - Echocardiography</b>			
	Echo date		• Date of pre-procedure echo



			<ul style="list-style-type: none"> <li>• Date format: DD/MMM (3 first letters)/YY</li> </ul>
Echo Type	TTE TEE		<ul style="list-style-type: none"> <li>• Transthoracic echocardiogram</li> <li>• Transesophageal echocardiogram</li> </ul>
LVEF	%		<ul style="list-style-type: none"> <li>• Left ventricular ejection fraction obtained by echocardiography</li> </ul>
LVMI	g/m <sup>2</sup>		<ul style="list-style-type: none"> <li>• Left ventricular mass index</li> </ul>
SPAP	mm/Hg		<ul style="list-style-type: none"> <li>• Pulmonary artery systolic pressure obtained by echocardiography</li> </ul>
MPAP	mmHg		<ul style="list-style-type: none"> <li>• Pulmonary artery mean pressure obtained by echocardiography</li> </ul>
LVOT	mm		<ul style="list-style-type: none"> <li>• Left ventricular outflow tract</li> </ul>
AoV annulus size	mm		<ul style="list-style-type: none"> <li>• Echocardiographic measurement of aortic valve annulus size</li> </ul>
Mean transvalvular gradient	mm		<ul style="list-style-type: none"> <li>• Mean LV/Ao transvalvular gradient obtained by echocardiography</li> </ul>
AoV EOA	cm <sup>2</sup>		<ul style="list-style-type: none"> <li>• Echocardiographic measurement of aortic valve effective orifice area</li> </ul>
AR	None +1/Trivial +2/Mild +3/Moderate +4/Severe		<ul style="list-style-type: none"> <li>• Aortic valve regurgitation grading by echocardiography</li> </ul>
MR	None +1/Trivial +2/Mild +3/Moderate +4/Severe		<ul style="list-style-type: none"> <li>• Mitral valve regurgitation grading by echocardiography</li> </ul>
MAC	None Mild Moderate Severe		<ul style="list-style-type: none"> <li>•</li> </ul>
TR	None +1/Trivial +2/Mild		<ul style="list-style-type: none"> <li>• Tricuspid valve regurgitation grading by echocardiography</li> </ul>



		+3/Moderate +4/Severe	
	LAV	ml	<ul style="list-style-type: none"> <li>• Left atrial volume measurement by echocardiography</li> </ul>
	LAVI	ml/m <sup>2</sup>	<ul style="list-style-type: none"> <li>• Left atrial volume index measurement by echocardiography</li> </ul>
	Mitral E/A		<ul style="list-style-type: none"> <li>• Ratio of early (E) to late diastolic mitral inflow velocity (A)</li> </ul>
	E/E'		<ul style="list-style-type: none"> <li>• Ratio of early diastolic inflow (E) to annulus (E') velocity</li> </ul>
	DT	msec	<ul style="list-style-type: none"> <li>• Diastolic time measurement by echocardiography</li> </ul>
<b>Patient screening - Eligibility</b>			
	<b>Surgical Risk</b>		
	<b>Critical preoperative state</b>	No	<ul style="list-style-type: none"> <li>• In previous week, no history of:                             <ul style="list-style-type: none"> <li>• VT/VF or aborted sudden death</li> <li>• Pre-operative cardiac massage</li> <li>• Pre-operative ventilation before anaesthetic</li> <li>• Pre-operative acute renal failure (anuria or oliguria &lt;10ml/hr)</li> </ul> </li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• In previous week, history of:                             <ul style="list-style-type: none"> <li>• VT/VF or aborted sudden death</li> <li>• Pre-operative cardiac massage</li> <li>• Pre-operative ventilation before anaesthetic</li> <li>• Pre-operative acute renal failure (anuria or oliguria &lt;10ml/hr)</li> </ul> </li> </ul>
	<b>Emergency T-AVI</b>	No	<ul style="list-style-type: none"> <li>• Operation does not need to be scheduled before beginning of next working day</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Operation should be scheduled before beginning of next working day</li> </ul>
	Log EuroSCORE	%	<ul style="list-style-type: none"> <li>• As calculated from input into T-AVI data base</li> </ul>
	STS score		<ul style="list-style-type: none"> <li>• Link to STS calculator</li> </ul>
	<b>Cardiac status:</b>		
	Mean aortic gradient > 40 mmHg	No – Yes	<ul style="list-style-type: none"> <li>•</li> </ul>



	Aortic valve area < 0.8 cm <sup>2</sup>	No – Yes	•
	NYHA Functional class II or greater	No – Yes	•
<b>Patient Reported Functional status</b>			
	Excessive fatigue/exhaustion	No – Yes	•
	Excessive weakness in ability to carry out basic ADLs	No – Yes	•
	Excessive slowness in ability to get up and go	No – Yes	•
	Restricted capacity to perform ADLs	No – Yes	•
	Other	No – Yes  If Yes, Specify	•
<b>Summary of screening assessment</b>			
	High surgical risk	No Yes	• High risk according to EuroSCORE
	Surgical/technical indications	<input type="checkbox"/> Porcelain aorta <input type="checkbox"/> Sternotomy re-do <input type="checkbox"/> Adhered graft <input type="checkbox"/> Other – Specify: _____	• Presence of surgical/technical contraindications to surgical AVR



	High comorbid burden	No Yes	<ul style="list-style-type: none"> <li>• Presence of at least one additional comorbidity including renal failure and severe pulmonary disease</li> </ul>
	High frailty	No Yes	<ul style="list-style-type: none"> <li>• Presence of at least three self-reported impairments of functional status</li> </ul>
	Main symptomatic indication for T-AVI	<input type="checkbox"/> SOB/CHF <input type="checkbox"/> Syncope <input type="checkbox"/> Angina	<ul style="list-style-type: none"> <li>• Most prevalent presentation due to severe aortic stenosis</li> </ul>
	Eligibility for T-AVI	No Yes	<ul style="list-style-type: none"> <li>• Multidisciplinary consensus decision</li> </ul>
	Wait time #2 Decision date		<ul style="list-style-type: none"> <li>• All required screening diagnostic tests are completed to allow decision</li> <li>• Patient is willing, able and ready to undergo T-AVI</li> <li>• Patient is placed on waiting on waiting list</li> </ul>
	Reason not surgical candidate	<input type="checkbox"/> Age <input type="checkbox"/> Comorbidities <input type="checkbox"/> Frailty <input type="checkbox"/> Other – Specify: _____	<ul style="list-style-type: none"> <li>•</li> </ul>
	Patient accepted for procedure, reason for procedure not done:	User input field	<ul style="list-style-type: none"> <li>•</li> </ul>
<b>Procedure – Transfemoral approach</b>			
	Transfemoral approach	No Yes	<ul style="list-style-type: none"> <li>•</li> </ul>
	Procedure date	Date	<ul style="list-style-type: none"> <li>•</li> </ul>
	Arterial Access	Femoral Other (Specify)	<ul style="list-style-type: none"> <li>•</li> </ul>
	Anaesthesia	General Local	<ul style="list-style-type: none"> <li>• General anaesthesia: intubation (ETT/LMA)</li> <li>• Local anaesthesia: epidural, nerve block, local lidocaine</li> </ul>



	Delivery sheath size	F	<ul style="list-style-type: none"> <li>• Size of TFA TAVI vascular access sheath measured in French size</li> </ul>
	Intra-procedure echo	No	<ul style="list-style-type: none"> <li>• No use of intraprocedure echocardiography</li> </ul>
		Yes if Yes, TEE TTE	<ul style="list-style-type: none"> <li>• Use of intraprocedure echocardiography</li> <li>• Transesophageal echocardiography</li> <li>• Transthoracic echocardiography</li> </ul>
	AoV annulus size (echo)	mm	<ul style="list-style-type: none"> <li>• Intra-procedure AV annulus size measured by echocardiography</li> <li>• Or pre-assessed AV annulus size</li> </ul>
	Pre-dilatation valvuloplasty	No Yes	<ul style="list-style-type: none"> <li>• AV balloon valvuloplasty performed pre-TFA TAVI deployment</li> </ul>
	Rapid RV pacing rate	beats/min	<ul style="list-style-type: none"> <li>• Rapid ventricular pacing rate used for T-AVI deployment</li> </ul>
	Post-deployment valvuloplasty	No Yes	<ul style="list-style-type: none"> <li>• Post-deployment T-AVI balloon valvuloplasty</li> </ul>
	Puncture time	Time	<ul style="list-style-type: none"> <li>• Initial puncture time of femoral artery used for delivery system</li> </ul>
	Delivery sheath removal time	Time	<ul style="list-style-type: none"> <li>• Time of removal of T-AVI delivery sheath</li> </ul>
	Intubation	No Yes If Yes provide Extubate information	<ul style="list-style-type: none"> <li>• No intubation used for procedure</li> </ul>
	Intubation time	Time	<ul style="list-style-type: none"> <li>• Intubation time</li> </ul>
	Extubate post procedure	Yes No	<ul style="list-style-type: none"> <li>•</li> </ul>
	Total fluoroscopy time	Time	<ul style="list-style-type: none"> <li>• Total fluoroscopy time required to complete procedure</li> </ul>
	Total contrast volume	ml	<ul style="list-style-type: none"> <li>• Total volume of contrast media used to complete procedure</li> </ul>
	Vascular Closure	Vascular closure device Surgical repair	<ul style="list-style-type: none"> <li>•</li> </ul>
	If Vascular closure is selected then select	Hemostasis achieved Surgical repair required	<ul style="list-style-type: none"> <li>•</li> </ul>



	Vascular closure device outcome option		
<b>Procedure – Transapical approach</b>			
	Transapical Approach	Yes No	•
	Procedure date	Date	•
	Reasons for apical	PVD Small vessel calibre Unfolded aorta Posterior aorta Other Other: Specify	<ul style="list-style-type: none"> <li>• TAA selected due to presence of severe peripheral vascular disease</li> <li>• TAA selected due to small femoral artery size</li> <li>• TAA selected due to unfolded aorta identified by x-ray or CT</li> <li>• TAA selected due to other reason</li> <li>• Specify indication for TAA</li> </ul>
	Delivery sheath size	F	• Size of TAA TAVI vascular access sheath measured in French size
	Intra-procedure echo	No	• No use of intraprocedure echocardiography
		Yes if yes, select intraprocedure echo type option: TEE TTE	<ul style="list-style-type: none"> <li>• Use of intraprocedure echocardiography</li> <li>• Transesophageal echocardiography</li> <li>• Transthoracic echocardiography</li> </ul>
	Rapid RV pacing rate	beats/min	• Rapid ventricular pacing rate used for T-AVI deployment
	Post-deployment valvuloplasty	No Yes	• Post-deployment T-AVI balloon valvuloplasty
	AoV annulus size	mm	<ul style="list-style-type: none"> <li>• Intra-procedure AV annulus size measured by echocardiography</li> <li>• Or pre-assessed AV annulus size</li> </ul>
	Pre-dilatation valvuloplasty	No Yes	• AV balloon valvuloplasty performed pre-transapical TAVI deployment
	Skin incision time	Time	• Initial incision time
	Skin closure time	Time	• Time of removal of transapical T-AVI delivery sheath
	Intubation	No	• No intubation used for procedure



		Yes If Yes provide time and Extubate information	
	Intubation time	Time	<ul style="list-style-type: none"> <li>Intubation time</li> </ul>
	Extugate post proceured	No Yes	<ul style="list-style-type: none"> <li></li> </ul>
	Total fluoroscopy time	Time	<ul style="list-style-type: none"> <li>Total fluoroscopy time required to complete procedure</li> </ul>
	Total contrast volume	ml	<ul style="list-style-type: none"> <li>Total volume of contrast media used to complete procedure</li> </ul>
	Vascular Closure	Percutaneous Surgical	<ul style="list-style-type: none"> <li></li> </ul>
	If Percutaneous is selected then select Vasuclar closure device outcome option	Hemostasis achieved Surgical repair required	<ul style="list-style-type: none"> <li></li> </ul>
	Reinforced repair required	No Yes	<ul style="list-style-type: none"> <li>Reinforced surgical repair required to achieve hemostasis</li> </ul>
	Chest tube left in situ	No Yes	<ul style="list-style-type: none"> <li>Chest tube or pigtail inserted and left in situ at end of procedure</li> </ul>
	Temporary pacing wires left in situ	No Yes	<ul style="list-style-type: none"> <li>Temporary pacing wires inserted and left in situ at end of procedure</li> </ul>
<b>Procedure – Valve/Delivery System Detail</b>			
	Valve type	Medtronic CORE Edwards LifeSciences Other - specify	<ul style="list-style-type: none"> <li>Manufacturer of prosthetic valve</li> </ul>
	Valve size	mm	<ul style="list-style-type: none"> <li>Size of prosthetic valve</li> </ul>
	Valve model number		<ul style="list-style-type: none"> <li>Model number of prosthetic valve</li> </ul>
	Valve serial number		<ul style="list-style-type: none"> <li>Serial number of prosthetic valve</li> </ul>
	Delivery system	Transarterial approach Edwards RetroFlex I/II or III	



		Other – specify	
		Transapical approach	
	Valve deployment	Successful	<ul style="list-style-type: none"> <li>Prosthetic valve deployed and implanted</li> </ul>
		Unsuccessful – specify: Vascular access passage Unable to cross valve Embolization Device-related failure Patient status deterioration Other – specify	<ul style="list-style-type: none"> <li>Main reason for failure to deploy and/or implant prosthetic valve</li> </ul>
	Additional valve deployment	No	<ul style="list-style-type: none"> <li>Single prosthetic valve deployed during T-AVI</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Two prosthetic valves deployed during T-AVI</li> </ul>
	Valve position	Optimal High Low	<ul style="list-style-type: none"> <li></li> </ul>
	AR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>Grading of aortic regurgitation post-deployment</li> </ul>
	Paravalvular leak	None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>Grading of aortic paravalvular leak post-deployment</li> </ul>



PART 3: Intra/Post-Procedure Details

Intra/Post-Procedure Details – Intra/Early Post-Procedure Support in initial 24 hours post-procedure (< 24 hours)

Section 1: Intra/early post- procedure support < 24 hrs

Major arrhythmia	No	<ul style="list-style-type: none"> <li>Absence of intra-procedure major arrhythmia</li> </ul>
	Yes Sinus arrest AV Block III VT/VF	<ul style="list-style-type: none"> <li>Major intra-procedure arrhythmia – self-terminating or treated</li> </ul>
Low output syndrome	No	<ul style="list-style-type: none"> <li>Appropriate intra-procedure cardiac output</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Sustained decreased intra-procedure cardiac output resulting in hemodynamic instability, signs and symptoms of cardiogenic shock, myocardial ischemia, and/or persistent need for hemodynamic support</li> </ul>
Vascular access hemorrhage	No	<ul style="list-style-type: none"> <li>No major intra-procedure hemorrhagic complications</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Intra-procedure vascular access hemorrhage requiring blood products, fluid resuscitation, surgical intervention and/or other treatment</li> </ul>
Blood products	No	<ul style="list-style-type: none"> <li>No blood products administered intra-procedure</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Administration of blood products intra-procedure including PRBCs, autologous blood, fresh frozen plasma, platelets and/or albumin</li> </ul>
Cardiac tamponade	No	<ul style="list-style-type: none"> <li>No intra-procedure tamponade</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Intra-procedure tamponade</li> </ul>
Emergency cardiac surgery	No	<ul style="list-style-type: none"> <li>No additional cardiac surgery at time of T-AVI</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Cardiac surgery performed at time of T-AVI</li> </ul>
Coronary obstruction	No	<ul style="list-style-type: none"> <li>No coronary obstruction visible on post-procedure coronary angiography</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Coronary obstruction visible on post-procedure coronary angiography</li> </ul>
Intra-procedure PCI	No	<ul style="list-style-type: none"> <li>No intra-procedure PCI</li> </ul>
	Yes	<ul style="list-style-type: none"> <li>Intra-procedure PCI performed due to T-AVI-related coronary</li> </ul>



			obstruction
Aortic root dissection/ rupture	No		<ul style="list-style-type: none"> <li>No intra-procedure aortic root dissection or rupture</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Intra-procedure aortic root dissection or rupture</li> </ul>
LV rupture	No		<ul style="list-style-type: none"> <li>No intra-procedure rupture of left ventricle</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Intra-procedure rupture of left ventricle</li> </ul>
Intubation	No		<ul style="list-style-type: none"> <li></li> </ul>
Extubated in OR/Cath Lab prior to transfer to recovery area	Yes if Yes Extubation details		
	N/A		<ul style="list-style-type: none"> <li>Remains intubated and ventilated at time of transfer</li> </ul>
CPR required	No		<ul style="list-style-type: none"> <li></li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Extubated in OR/CL</li> </ul>
Death	If Yes to Extubated in OR/Cath Lab: No		<ul style="list-style-type: none"> <li></li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Alive at end of procedure</li> <li>Pronounced dead at end of procedure</li> </ul>
<b>Section 2: Support required in initial 24 hours post-procedure (&lt; 24 hours)</b>			
Patient admitted post- procedure	No		
	Yes If Yes: ICU CCU Ward Other – specify		
Hemodynamic support	No		<ul style="list-style-type: none"> <li>No hemodynamic support required in initial 24 hours after T-AVI</li> </ul>
	Yes		<ul style="list-style-type: none"> <li>Hemodynamic support required in initial 24 hours after T-AVI</li> </ul>
	Timing: Intra-procedure		<ul style="list-style-type: none"> <li>Hemodynamic support initiated during procedure and maintained</li> </ul>



		Post-procedure	<ul style="list-style-type: none"> <li>Hemodynamic support initiated after procedure but &lt; 24 hrs</li> </ul>
		Type: Vasoactive medications IABP ECMO VAD	<ul style="list-style-type: none"> <li>Continuous infusion and titration of vasoactive agents</li> <li>Insertion of intra-aortic balloon pump</li> <li>Initiation of extra-corporeal membrane oxygenation</li> <li>Implantation of ventricular assist device</li> </ul>
	Respiratory support	No	<ul style="list-style-type: none"> <li>No mechanical ventilatory support required &lt; 24 hours</li> </ul>
		Yes If Yes: Prolonged intubation Re-intubation Other – specify	<ul style="list-style-type: none"> <li>Mechanical ventilatory support required &lt; 24 hours</li> </ul>
<b>Section 3: Early recovery in initial 24 hours post-procedure (&lt; 24 hours)</b>			
	Acute limb ischemia < 24 hours	No	<ul style="list-style-type: none"> <li>Adequate limb perfusion within 24 hours post-procedure</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Signs and symptoms of limb ischemia 24 hours post-procedure</li> </ul>
	Blood products < 24 hours	No	<ul style="list-style-type: none"> <li>No blood products administered within 24 hours post-procedure</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Administration of blood products intra-procedure including PRBCs, autologous blood, fresh frozen plasma, platelets and/or albumin</li> </ul>
	Myocardial infarction	No	<ul style="list-style-type: none"> <li>No myocardial infarction within 24 hours post-procedure</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Myocardial infarction within 24 hours post-procedure</li> </ul>
	Interventional cardiology procedure < 24 hours	No	<ul style="list-style-type: none"> <li>No emergency interventional cardiology procedure performed within 24 hours post-procedure (e.g. emergency PCI)</li> </ul>
		Yes If Yes Check PCI or Other provide description	<ul style="list-style-type: none"> <li>Emergency interventional cardiology procedure performed within 24 hours post-procedure (e.g. emergency PCI)</li> </ul>
	Surgery < 24 hours	No	<ul style="list-style-type: none"> <li>No emergency surgery performed within 24 hours post-procedure (e.g. emergency PCI)</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Emergency surgery performed within 24 hours post-procedure</li> </ul>
		Pacemaker	
		Evacuation of hematoma	



		Vascular repair	
		Debridement	
		Other - specify	
	Post-procedure hemoglobin	If male: > 140 g/L 90 – 140 g/L < 90 g/L If female: > 120 g/L 80 – 120 g/L < 80 g/L	
<b>&gt;24 hrs in-hospital complications (24 hours post-procedure to discharge)</b>			
	Late in-hospital complication from 24 hours post-procedure to discharge	No	<ul style="list-style-type: none"> <li>No complication experienced 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>One or more complications experienced 24 hours post-procedure to time of discharge</li> </ul>
<b>Cardiac</b>			
	Myocardial ischemia/infarction	No	<ul style="list-style-type: none"> <li>Absence of myocardial ischemia or infarction 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Absence of myocardial ischemia or infarction 24 hours post-procedure to time of discharge</li> </ul>
	Low cardiac output syndrome	No	<ul style="list-style-type: none"> <li>Appropriate cardiac output maintained 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Sustained decreased cardiac output resulting in hemodynamic instability, signs and symptoms of cardiogenic shock, myocardial ischemia, and/or persistent need for hemodynamic support 24 hours post-procedure to time of discharge</li> </ul>
	Cardiac arrest	No	<ul style="list-style-type: none"> <li>Absence of cardiac arrest requiring resuscitation</li> </ul>



		Yes	<ul style="list-style-type: none"> <li>• Cardiac arrest sustained 24 hours post-procedure to time of discharge</li> </ul>
	Major arrhythmia	No	<ul style="list-style-type: none"> <li>• Absence of sustained major arrhythmia requiring intervention post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Sustained major arrhythmia requiring intervention post-procedure to time of discharge</li> </ul>
		Sinus arrest	
		AV Block III	
		VT/VF	
	New onset AF/Aflutter	No	<ul style="list-style-type: none"> <li>• No new onset of atrial fibrillation or flutter 24 hours post-procedure to time of admission</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• New onset of atrial fibrillation or flutter 24 hours post-procedure to time of admission</li> </ul>
	Cardiac tamponade	No	<ul style="list-style-type: none"> <li>• Absence of cardiac tamponade 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Cardiac tamponade post-procedure to time of discharge</li> </ul>
<b>Neurologic</b>			
	Cerebrovascular event	No	<ul style="list-style-type: none"> <li>• Absence of cerebrovascular event 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Cerebrovascular event 24 hours post-procedure to time of discharge</li> </ul>
		TIA	<ul style="list-style-type: none"> <li>• Transient ischemic attack with resolution &lt; 24 hours</li> </ul>
		RIND	<ul style="list-style-type: none"> <li>• Reversible ischemic neurological deficit with resolution within 24 to 72 hours</li> </ul>
		CVA	<ul style="list-style-type: none"> <li>• Cerebrovascular attack with effects extending beyond 72 hours</li> </ul>
		Continuous coma > 24 hours	<ul style="list-style-type: none"> <li>• Glasgow coma scale &lt; 6 for longer than 24 hours</li> </ul>
<b>Pulmonary</b>			
	Prolonged ventilation after 24 hours	No	<ul style="list-style-type: none"> <li>• No prolonged intubation/ventilation after initial 24 hours post-procedure</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Prolonged intubation/ventilation after initial 24 hours post-procedure</li> <li>• On-going or re-intubation</li> </ul>



	Pulmonary embolism	No	<ul style="list-style-type: none"> <li>Absence of pulmonary embolism 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Pulmonary embolism 24 hours post-procedure to time of discharge</li> </ul>
	Pneumonia	No	<ul style="list-style-type: none"> <li>Absence of pneumonia 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Pneumonia 24 hours post-procedure to time of discharge</li> </ul>
<b>Vascular</b>			
	Acute limb ischemia	No	<ul style="list-style-type: none"> <li>Absence of signs and symptoms of acute limb ischemia 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Signs and symptoms of acute limb ischemia 24 hours post-procedure to time of discharge</li> </ul>
	Hemorrhage	No	<ul style="list-style-type: none"> <li>Absence of vascular access/surgical hemorrhage 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Vascular access/surgical hemorrhage 24 hours post-procedure to time of discharge</li> </ul>
	Iliac/femoral artery dissection	No	<ul style="list-style-type: none"> <li>Absence of iliac/femora artery dissection 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Iliac/femoral artery dissection 24 hours post-procedure to time of discharge</li> </ul>
		N/A	<ul style="list-style-type: none"> <li>Not applicable – transapical approach</li> </ul>
	Aortic dissection after 24 hours	No	<ul style="list-style-type: none"> <li>Absence of aortic dissection 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Aortic dissection 24 hours post-procedure to time of discharge</li> </ul>
<b>Sepsis/SIRS</b>			
	Access site infection	No	<ul style="list-style-type: none"> <li>Absence of signs and symptoms of access site infection</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Signs and symptoms of access site infection</li> </ul>
	Antibiotic treatment initiated	No	<ul style="list-style-type: none"> <li>No antibiotic treatment initiated 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Antibiotic treatment initiated 24 hours post-procedure to time of</li> </ul>



			discharge
	Multi-system organ failure	No	<ul style="list-style-type: none"> <li>Absence of multi-system organ failure 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>Multi-system organ failure 24 hours post-procedure to time of discharge resulting in septic shock and/or other major complication</li> </ul>
<b>Renal</b>			
	eGFR – >24 hrs post-procedure	> 50 mls/min	<ul style="list-style-type: none"> <li>eGFR measured 48 hours post-procedure</li> </ul>
		≤ 50 mls/min	
	Creatinine – >24 hrs post-procedure	< 120 μmol/L	<ul style="list-style-type: none"> <li>Serum creatinine measured 48 hours post-procedure</li> </ul>
		120 – 200 μmol/L	
		≥ 200 μmol/L	
	New Initiation of dialysis	No Yes	<ul style="list-style-type: none"> <li></li> </ul>
<b>Gastrointestinal</b>			
	GI hemorrhage	No	<ul style="list-style-type: none"> <li>Absence of GI hemorrhage 24 hours post-procedure to time of discharge</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>GI hemorrhage 24 hours post-procedure to time of discharge</li> </ul>
	Other GI complication	No	<ul style="list-style-type: none"> <li>Absence of other GI complication 24 hours post-procedure to time of discharge</li> </ul>
		Yes – specify	<ul style="list-style-type: none"> <li>Other GI complication 24 hours post-procedure to time of discharge</li> </ul>
<b>Lab results &gt;24 hrs post-procedure</b>			
	Hemoglobin – 24 hrs post-procedure	if male: > 140 g/L 90 – 140 g/L < 90 g/L if female: > 120 g/L 80 – 120 g/L < 80 g/L	<ul style="list-style-type: none"> <li>Hemoglobin measured 48 hours post-procedure</li> </ul>



	NT-ProBNP	ng/ml	<ul style="list-style-type: none"> <li>NT-ProBNP serum level measured 48 hours post-procedure</li> </ul>
<b>Disposition information</b>			
	In hospital mortality	Yes If Yes, provide death date and time	<ul style="list-style-type: none"> <li>Alive at time of discharge from T-AVI hospital</li> </ul>
		No	<ul style="list-style-type: none"> <li>Pronounced dead in T-AVI hospital</li> </ul>
	Disposition	Discharged from TAVI Hospital Transferred to community hospital	<ul style="list-style-type: none"> <li></li> </ul>
	Discharged from T-AVI hospital date	Date	<ul style="list-style-type: none"> <li>Date of discharge from T-AVI hospital</li> <li>Discharge home or transfer to referring/community hospital</li> </ul>
	Transferred to referring/community hospital date	Date	<ul style="list-style-type: none"> <li>Date of discharge from referring/community hospital that admitted patient following transfer from T-AVI hospital</li> </ul>
<b>Discharge medications</b>			
	Aspirin	No Yes	<ul style="list-style-type: none"> <li>Regular aspirin, any dose</li> </ul>
	Anti-platelet	No Yes	<ul style="list-style-type: none"> <li>E.g. clopidogrel , IIB or IIIa inhibitor or Other Specify</li> </ul>
	Anticoagulant	No Yes If Yes, please check off Walfarin, LMWH, Heparin and other (provide description)	<ul style="list-style-type: none"> <li>Includes oral, subcutaneous or intravenous agents</li> <li>Options Walfarin, LMWH, Heparin, Other Specify</li> </ul>
	Beta blocker	No Yes	
	ACE-I	No Yes	
	ARB	No Yes	



	Calcium channel blocker	No Yes	
	Diuretic	No Yes	<ul style="list-style-type: none"> <li>Includes oral and intravenous agents</li> </ul>
	Digoxin	No Yes	
	Nitrates	No Yes	<ul style="list-style-type: none"> <li>Includes sublingual, transdermal, oral, intravenous agents</li> </ul>
	Cholesterol-lowering statin	No Yes	
	Amiodarone	No Yes	<ul style="list-style-type: none"> <li>Includes oral and intravenous agents</li> </ul>
	Other cardiac medication	No Yes, Specify	<ul style="list-style-type: none"> <li>List other cardiac medications</li> </ul>
<b>Pre-discharge cardiac echo</b>			
	Echo date		<ul style="list-style-type: none"> <li>Date of pre-procedure echo</li> <li>Date format: DD/MMM (3 first letters)/YY</li> </ul>
	Type	TTE TEE	<ul style="list-style-type: none"> <li>Transthoracic echocardiogram</li> <li>Transesophageal echocardiogram</li> </ul>
	LVEF	%	<ul style="list-style-type: none"> <li>Left ventricular ejection fraction obtained by echocardiography</li> </ul>
	LVMI	g/m <sup>2</sup>	<ul style="list-style-type: none"> <li>Left ventricular mass index</li> </ul>
	SPAP	mm/Hg	<ul style="list-style-type: none"> <li>Pulmonary artery systolic pressure obtained by echocardiography</li> </ul>
	MPAP	mmHg	<ul style="list-style-type: none"> <li>Pulmonary artery mean pressure obtained by echocardiography</li> </ul>
	LVOT	cm <sup>2</sup>	<ul style="list-style-type: none"> <li>Left ventricular outflow tract</li> </ul>
	AoV annulus size	mm	<ul style="list-style-type: none"> <li>Echocardiographic measurement of aortic valve annulus size</li> </ul>
	Mean transvalvular gradient	mmHg	<ul style="list-style-type: none"> <li>Mean LV/Ao transvalvular gradient obtained by echocardiography</li> </ul>



	AoV EOA	cm <sup>2</sup>	<ul style="list-style-type: none"> <li>Echocardiographic measurement of aortic valve effective orifice area</li> </ul>
	AR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>Aortic valve regurgitation grading by echocardiography</li> </ul>
	MR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>Mitral valve regurgitation grading by echocardiography</li> </ul>
	MAC	None Mild Moderate Severe	
	TR	None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>Tricuspid valve regurgitation grading by echocardiography</li> </ul>
	LAV	ml	<ul style="list-style-type: none"> <li>Left atrial volume measurement by echocardiography</li> </ul>
	LAVI	ml/m <sup>2</sup>	<ul style="list-style-type: none"> <li>Left atrial volume index measurement by echocardiography</li> </ul>
	Mitral E/A		<ul style="list-style-type: none"> <li>Ratio of early (E) to late diastolic mitral inflow velocity (A)</li> </ul>
	E/E'		<ul style="list-style-type: none"> <li>Ratio of early diastolic inflow (E) to annulus (E') velocity</li> </ul>
	DT	msec	<ul style="list-style-type: none"> <li>Diastolic time measurement by echocardiography</li> </ul>



Intra/Post-Procedure Details – Follow-up			
Follow-up time point	Drop-down list selection of follow-up time points: <ul style="list-style-type: none"> <li>30 days</li> <li>90 days</li> <li>6 months</li> <li>12 months</li> <li>24 months</li> </ul>	<ul style="list-style-type: none"> <li>Input follow-up data for multiple follow-up time points. The user input fields are same for all follow-up time points.</li> <li>If patient death is selected for a follow-up time point (e.g. 6 months), the follow-up time points after that (i.e. 12 months and 24 months) will not show up in the drop-down list for selection.</li> </ul>	
Patient death	If checked, provide Death Date and Time and cause of death	<ul style="list-style-type: none"> <li>Pronounced dead at time of follow-up</li> <li>Only one of the three checkboxes 'Patient death', 'Follow-up done' and 'Follow-up not done' can be selected.</li> </ul>	
Follow-up done	If checked, provide details of follow-up at this time point	<ul style="list-style-type: none"> <li>Alive at time of follow-up and follow-up is done.</li> <li>Only one of the three checkboxes 'Patient death', 'Follow-up done' and 'Follow-up not done' can be selected.</li> </ul>	
Hospital re-admission since T-AVI discharge	No	<ul style="list-style-type: none"> <li>No hospital re-admission since discharge from T-AVI</li> </ul>	
	Yes	<ul style="list-style-type: none"> <li>Re-admitted to hospital following discharge from T-AVI</li> </ul>	
ED visit since discharge from T-AVI	No	<ul style="list-style-type: none"> <li>No emergency department visit since discharge from T-AVI</li> </ul>	
	Yes	<ul style="list-style-type: none"> <li>Emergency department visit since discharge from T-AVI</li> </ul>	
Cause of re-admission or visit to ED	T-AVI complication		
	CHF-SOB		
	Angina		
	Syncope		
	Other - specify		
Follow-up T-AVI appointment date	Date	<ul style="list-style-type: none"> <li>Date of follow-up</li> </ul>	
Follow-up by	T-AVI hospital MD	<ul style="list-style-type: none"> <li>Member of the T-AVI medical team at implanting hospital</li> </ul>	
	Other specialist	<ul style="list-style-type: none"> <li>Other cardiologist, cardiac surgeon or internist</li> </ul>	
	Other	<ul style="list-style-type: none"> <li>Specify</li> </ul>	



	Follow-up type	Patient visit	<ul style="list-style-type: none"> <li>• Patient seen in clinic or office</li> </ul>
		Telephone assessment	<ul style="list-style-type: none"> <li>• Patient assessed by telephone</li> </ul>
		Other	<ul style="list-style-type: none"> <li>• Specify</li> </ul>
	Functional class NYHA	Class I-IV	<ul style="list-style-type: none"> <li>• N/A – Absence of heart failure and asymptomatic</li> <li>• Class I – Mild: No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</li> <li>• Class II - Mild: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</li> <li>• Class III - Moderate: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</li> <li>• Class IV – Severe: Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</li> </ul>
	CCS Class	<p>I</p> <p>II</p> <p>III</p> <p>IVa-d</p>	<ul style="list-style-type: none"> <li>• Class I: Ordinary physical activity such as walking, climbing stairs does not cause angina. Angina (occurs) with strenuous, rapid or prolonged exertion at work or recreation</li> <li>• Class II: Slight limitation of ordinary activity. Angina occurs on walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions</li> <li>• Class III: Marked limitations of ordinary physical activity. Angina occurs on walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at a normal pace.</li> <li>• Class IV: Inability to carry on any physical activity without discomfort - anginal symptoms may be present at rest.             <ul style="list-style-type: none"> <li>• IVa: Patient admitted to hospital and becomes relatively</li> </ul> </li> </ul>



			<p>asymptomatic with aggressive medical therapy</p> <ul style="list-style-type: none"> <li>• IVb: Patient admitted to hospital and continues to experience angina on maximal medical therapy and cannot be safely discharged home, but does not require IV nitroglycerin.</li> <li>• IVc: Patient admitted to hospital and maximal medical therapy, including IV nitroglycerin, fails to control symptoms or there is hemodynamic instability.</li> <li>• IVd: Cardiogenic shock</li> </ul>
	Echo done	No	<ul style="list-style-type: none"> <li>• No cardiac echocardiogram performed at follow-up</li> </ul>
		Yes	<ul style="list-style-type: none"> <li>• Cardiac echocardiogram performed at follow-up</li> </ul>
if yes	Echo date	Date	<ul style="list-style-type: none"> <li>• Date of follow-up echocardiogram</li> </ul>
	Echo location	T-AVI hospital	
		Other hospital	
		MD office/clinic	
	Summary of echo findings	LVEF (%)	<ul style="list-style-type: none"> <li>• Left ventricular ejection fraction obtained by echocardiography</li> </ul>
		Mean transvalvular gradient (mmHg)	<ul style="list-style-type: none"> <li>• Mean LV/Ao transvalvular gradient obtained by echocardiography</li> </ul>
		AoV annulus size (mm)	<ul style="list-style-type: none"> <li>• Echocardiographic measurement of aortic valve annulus size</li> </ul>
		AoV EOA (cm <sup>2</sup> )	<ul style="list-style-type: none"> <li>• Echocardiographic measurement of aortic valve effective orifice area</li> </ul>
		Echo AR None +1/Trivial +2/Mild +3/Moderate +4/Severe	<ul style="list-style-type: none"> <li>• Aortic valve regurgitation grading by echocardiography</li> </ul>
		Echo MR None +1/Trivial +2/Mild	<ul style="list-style-type: none"> <li>• Mitral valve regurgitation grading by echocardiography</li> </ul>



		+3/Moderate +4/Severe	
		SPAP (mm/Hg)	<ul style="list-style-type: none"> <li>Pulmonary artery systolic pressure obtained by echocardiography</li> </ul>
		MPAP (mm/Hg)	<ul style="list-style-type: none"> <li>Pulmonary artery mean pressure obtained by echocardiography</li> </ul>
Patient-reported functional assessment	Excessive fatigue/exhaustion No Yes		<ul style="list-style-type: none"> <li>Patient self-reports feeling excessively fatigued with minimal level of activity</li> </ul>
	Excessive weakness in ability to carry out basic ADLs No Yes		<ul style="list-style-type: none"> <li>Patient self-reports feeling excessively weak in carrying out basic activities of daily living</li> </ul>
	Excessive slowness in ability to get up and go No Yes		<ul style="list-style-type: none"> <li>Patient is excessively slow in getting up from sitting position and stepping out to walk</li> </ul>
	Restricted capacity to perform ADLs No Yes		<ul style="list-style-type: none"> <li>Patient self-reports excessive restrictions in capacity to perform basic activities of daily living</li> </ul>
	Other, Specify		<ul style="list-style-type: none"> <li>Patient self-reports</li> </ul>
Follow-up not done	If checked, no input for this follow-up time point		<ul style="list-style-type: none"> <li>Only one of the three checkboxes 'Patient death', 'Follow-up done' and 'Follow-up not done' can be selected.</li> </ul>