STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 1 of 33 Version: 2

Transcatheter Aortic Valve Implantation (TAVI)
Standard Operating Procedure LocSSIP
UHL Cardiology Cath Labs

Change Description	Reason for Change
☐ Change in format	X Trust requirement

APPROVERS	POSITION	NAME
Person Responsible for Procedure:	Consultant Cardiologist	Prof Jan Kovac Dr Elved Roberts
SOP Owner:	Charge Nurse	John Steele
Sub-group Lead:	Charge Nurse	John Steele

Appendices in this document:

Appendix 1: Cath Lab Team Brief / Debrief

Appendix 2: Cath Lab Safe Surgery Checklist

Appendix 3: TAVI Count Sheet

Appendix 4: Pathway of Care: Aortic Trans catheter (Percutaneous) Valve Implantation

Appendix 5: Pre and post care of a TAVI patient

Introduction and Background:

This Standard Operating Procedure outlines the patient pathway for those patients undergoing Transcatheter Aortic Valve Implantation (TAVI) in the Glenfield Cardiac Catheter Department. TAVI is an established treatment for severe symptomatic aortic stenosis, and alternative to open heart surgery. TAVI involves implanting a new biological aortic valve to treat the narrowed aortic valve due to Aortic Stenosis. The risks include bleeding, stroke (1-2%), death (1-5% If implanted trans-femorally, trans-subclavian, transaortic or trans apical and depending on other risk factors), misplacement of the valve or damage to the heart during the Procedure (<1%) and requiring permanent pace maker (10-20%).

Referral/List management and scheduling:

The referral for a Trans-catheter Aortic Valve Implantation (TAVI) will go directly to the TAVI MDT. If patient is appropriate to proceed with TAVI then a clinic appointment will be arranged. If not appropriate for TAVI then we will refer back to the referrer. All previous investigations will be checked and benefits and risks of

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
	, ,
Glenfield Hospital, Angiocatheter Suite	Page 2 of 33 Version: 2

the procedure will be discussed with the patient. Investigations for TAVI workup will be requested if needed from this visit. Once all relevant investigations have been completed a final discussion will be held by the MDT prior to listing. Prior to their procedure a TAVI clinic appointment will be arranged to re-discuss the risks and benefits.

A pre-assessment clinic appointment will be arranged and a TAVI pathway document will be commenced. This pathway will then be used to document the patient's journey from admission to discharge according to the UHL TAVI LocSSIP.

Patients are then added to the waiting list on HISS and breach date established by the Cardiac admissions team. The weekly catheter lab schedule is compiled based on availability of appropriate trained staff, procedure room availability and breach dates within the admissions office and patients booked accordingly.

Inpatient referrals will be directed to the TAVI MDT and if accepted will be referred on ICE.

Pre Admission (Elective Process)

The following information is required to be completed at pre admission

- Patient name
- Identification numbers, i.e. NHS number with or without hospital number
- Date of birth
- Gender
- Planned procedure
- Procedural Urgency
- Site and side of procedure if relevant
- Significant comorbidities
- Allergies, e.g. to latex or iodine
- Infection risk
- Body mass index
- Decision made and advice given regarding pre-procedure anticoagulation regime
- UHL nursing risk assessments to be completed
- Documentation of any pre-procedure concerns discussed with the consultant team
- Due to the comorbidities of this patient cohort a decision on performing the procedure will be made by the TAVI team.

Patient preparation:

For elective cases the patient will have been given a Patient information leaflet prior to arriving in the department. This will be sent in the post or given at the pre-assessment appointment.

The following information is required to be completed prior to the patient being collected for their procedure (Inpatients)/prior to admission to the Cardiology Department (day cases) and must be documented in the TAVI pathway and UHL safer surgery checklist which includes.

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 3 of 33 Version: 2

- If any non-standard equipment is required, this should be documented on the procedural listing form.
- All aspects of the WHO compliant pre-procedure checklist in the TAVI pathway will be completed.
- Full medical documentation
- EWS score / observation
- Consent / Confirmation
- Dentures
- Communication
- Blood results (U&E and FBC for all patients and INR check if patient is taking Warfarin/NOAC. Advice will also be sought regarding pre-procedural anticoagulation management (Warfarin/NOAC) if this is not documented on the procedural listing form.
- 4 units of blood cross-matched
- For local anaesthetic cases, 18G cannula in large vein and prophylactic IV antibiotics administered on request from Cardiac Catheter Department.
- Confirm post procedure bed available. General Anaesthetic Theatre recovery / ITU /CCU or for Local Anaesthesia CCU.
- All cases requiring anaesthetic support need to be entered on the ORMIS scheduling system.
- All trans-apical cases will need an ITU bed booking prior to the day of the procedure.

Workforce – staffing requirements:

All team staff members will have completed relevant role specific HELM training and any other appropriate training (e.g. revalidation/IRMER). Maintaining relevant and current training is the responsibility of the individual and is regularly checked as per the appraisal process. All new members of staff will have completed full induction training before independently working in their role. Progress and skill development is monitored and managed by the senior staff in the area with regular review. Visitors to the area are closely supervised according to UHL policy.

This procedure requires the following team to be present throughout the procedure:

For general anaesthetic femoral cases:

1 lead Cardiologist, a second operator, 1 Anaesthetist, 1 operating department practitioner, 1 imaging consultant, 1 valve loaders, 1 radiographer, 2 trained nurses, 1 electrophysiologist.

For general anaesthetic subclavian cases:

1 lead Cardiologist, a second operator, 1 Anaesthetist, 1 operating department practitioner, 1 imaging consultant, 1 valve loaders, 1 radiographer, 2 trained nurses, 1 electrophysiologist. Plus a theatre team to include 1 consultant surgeon, surgical assistant, 1 theatre scrub nurse, 1 room nurse / HCA.

For general anaesthetic trans-apical cases:

1 lead Cardiologist, a second operator, 1 Anaesthetist, 1 operating department practitioner, 1 imaging

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 4 of 33 Version: 2

consultant, 1 valve loaders, 1 radiographer, 1 trained nurse, 1 catheter lab assistant, 1 electrophysiologist. Plus a theatre team to include 1 consultant surgeon, surgical assistant, 1 theatre scrub nurse, 1 room nurse / HCA.

For local anaesthetic femoral cases:

1 lead Cardiologist, a second operator, 1 valve loaders, 1 radiographer, 2 trained nurses, 1 electrophysiologist.

In all cases these are minimum numbers, it is preferred to have 2 loaders for the valve and with training requirements other staff levels may be higher.

This procedure will be scheduled by the list coordinator as per the UHL IR policy.

- Lead Cardiologist Has the overall responsibility for the procedure and ensures that the team safety brief is completed at 08:30 in the morning and prior to the afternoon list is conducted by a suitably trained member of the medical team. They will also as part of the team be responsible for ensuring the safer surgery checklist is performed for each procedure and also ensure the team are aware of non-standard steps/procedures/equipment needs for the case. The consultant acts as IRMER practitioner and is responsible for documentation of the procedure by a suitably trained medical member of the team. Indicating any further treatment or discharge plans, ensures appropriate prescription including all verbal orders, and data capture requirements.
- Second Operator This may be a consultant or appropriately trained specialist registrar. They will be
 responsible for sterility of equipment and the appropriate preparation of the patient procedural site.
 Ensures accountable items counts are undertaken and ensures safe handling of sharps on the
 procedural trolley. The operator will also be responsible for checking the integrity of all equipment
 that is removed from the patient and signs the accountable items sheet. Prepares equipment for the
 procedure following appropriate practice. Working as part of the MDT to ensure safety of patient.
- Anaesthetist Responsible for caring for patients who require anaesthetic support during the procedure. The Anaesthetist will be responsible for reviewing the patient prior to the procedure and discussing any issues or complex cases with the lead cardiologist.
- **Operating Department Practitioner** Provides support to the Anaesthetist, ensuring continued monitoring of the patient and safe administration of medications.
- Valve Loader In some cases there will be a representative from the valve company to assist with loading the valve and provide clinical support, they will be supported by a UHL member of staff to ensure counts and safety is maintained. UHL Allied Health Professionals including Nurses and Radiographers will have received specific training from the valve companies to allow them to load valves. During this training they will complete a number of observed loads and complete a training log as well as develop an understanding of the equipment requirements for all devices. They will act as a resource for the rest of the team. The loader will ensure that there are adequate stocks of valves in the appropriate size for all the planned cases and make the lead cardiologist aware of any issues. The loader will prepare the procedure trollies prior to the procedure and ensure that an

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 5 of 33 Version: 2

instrument count is completed and recorded on the count sheet. Following the valve deployment the loader will support the medical team with the removal of sheaths and ensure all equipment checks are completed and post procedure counts are completed.

- Radiographer Prior to the case starting the radiographer will import the TAVI CT images to the Leonardo workstation allowing the operators access to review these images in the control room. During TAVI procedure the radiographer will scrub to maintain a sterile field whilst being responsibility for IRMER compliance ensuring radiation safety of patients and staff, ensuring correct patient imaging with optimum settings. Reinforcing staff compliance with the local rules providing support and advice in order to comply. Completing the imaging process ensuring images are archived, dose information is recorded, reporting and addressing any radiation concerns. Working as part of the MDT to ensure safety of patient, ensuring the safer surgery check list is completed.
- Catheter Lab Circulating Nurse Responsible for caring for the patient in the room, ensuring
 adequate handover to follow on team. Medicines management, through storage of medicines and
 the safe administration of IV medication during the procedure following cath lab verbal order
 guidance. Ensuring sterility of all equipment and ensuring that all equipment and stock is available
 for the procedure, liaising with the stock management company for shortages. Scanning all stock
 used to ensure replacements can be ordered. Liaising with the cath lab co-ordinator for any changes
 to the list or escalated care requirements. Working as part of the MDT to ensure safety of patient,
 ensuring the safer surgery check list is completed.
- Catheter Lab Scrub Nurse Responsible for sterility of equipment and the appropriate preparation of
 the patient procedural site. Instigates accountable items counts and ensures safe handling of sharps
 on the procedural trolley. Prepares equipment for the procedure following company / consultant
 training. Working as part of the MDT to ensure safety of patient, ensuring the safer surgery check list
 is completed. This role can be interchangeable with the valve loader depending on experience and
 competencies.
- Cardiac Physiologist Responsible for the monitoring of the patients, connecting ECG monitoring, setting up pressure transducer and monitoring oxygen saturations. Keeping a log throughout the case and identifying any abnormal readings. Providing pacing support for deployment of the valve and temporary pacing set up if any bradycardia identified. Working as part of the MDT to ensure safety of patient, ensuring the safer surgery check list is completed.

Ward checklist, and ward to procedure room handover:

The ward will complete the TAVI pathway check list and the WHO theatre checklist identifying any issues and informing the Cath Lab team of any concerns. This will include any issue with blood transfusions, access, mobility, mental acuity, allergies and observations.

See TAVI Pathway in the appendices.

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
	Neview date. August 2024
Glenfield Hospital, Angiocatheter Suite	Page 6 of 33 Version: 2

Procedural Verification of Site Marking:

Site marking is not required, this procedure is performed via both femoral arteries.

Team Safety Briefing:

Prior to commencement of any elective, procedural list a 'Safety Briefing' which involves key members of the team as a minimum (ideally all the team) must take place.

- A minimum of: the primary operator and if allocated the second operator, 1 radiographer, 1 physiologist and both cath-lab nurses will be present at the team briefing and will be responsible for cascading handover to any other team members that join the procedure during the procedure.
- The purpose of the brief is to discuss the sessions' list schedule of planned procedures.
- The area used should be quiet and free from interruptions and preferably should be in the appropriate cath lab.
- The brief may be led by any designated member of the team.
- All staff members of the procedural team are named for the session and roles identified and written on the white board.
- The procedural list will be updated on the master board in reception as changes happen, the coordinator will inform the room team and operator of any changes at an appropriate time verbally. Wards will be informed of cancellations and additions as soon as possible.
- Any nonstandard steps identified and plans put in place if necessary.
- Equipment checks should have already been performed and any issues highlighted, and actions put in place to address if required.
- The first patient will only be sent for once the team brief has been completed.

Sign In:

The Sign In and Time Out are safety processes whereby the prompts on the checklist ensure verification of the correct patient, procedure.

- Conscious and coherent patients should actively be encouraged to participate in these processes.
- The Sign In verification process must be performed by two team members, one will be the radiographer and the other will also be involved in the procedure.
- The questions will be undertaken verbally in a clear, precise and audible tone, with the patient.
- The process must have both the two's checkers full attention to confirm sign in. No other task should be undertaken until this is completed.

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021	
Trust Reference Number: C64/2019	Revision date: August 2021	
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024	
Glenfield Hospital, Angiocatheter Suite	Page 7 of 33 Version: 2	

Time Out:

The Time Out must be undertaken with all the team present and everyone must engage and must give their full attention.

- The steps on the checklist must be led by a trained healthcare professional in a clear and audible manner.
- All team members must 'stop and pause' whilst the checklist questions are asked and responded to, hence this part of the safety process is known as 'time out'.
- If there is an interruption, the 'time out' must be suspended and recommenced.
- Every team member is valuable and should feel comfortable and at ease to raise any questions or concerns they have relating to the case at this time.
- The patient should once again be included where possible in the time out.
- Team members must not enter or leave the procedural room during this time.

Performing the procedure:

As well as a fully stocked Cardiac Catheter Lab a TAVI procedure requires:

- Standard Trolley
- Long trolley
- Angiopack
- Valve pack
- 1 box of 500ml NaCl 0.9% (plus frozen and cold available)
- Chloraprep 26ml
- 5fr, 7fr and 9fr femoral sheaths
- 2x 6fr Angled pigtail catheter
- 6fr AL 1
- 6fr JR 4
- Exchange J-tip wire 260cm 0.35"
- Straight standard wire 145cm 0.35"
- Extra stiff wire 260cm
- Confida or Safari wire
- Extra Kimal needle
- Pressure line
- Gallipot
- 3way tap
- Temporary pacing wire
- Pacing connectors
- Long floppy extensions
- Intensifier covers

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester MHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 8 of 33 Version: 2

- Proglide
- Appropriate large sheath for device
- At least 2 valves of the appropriate size and model

After completing the pre-procedural safety checks, patient will be assisted lying flat on the operating table and attached to ECG, blood pressure and pulse oximetry monitors. Gel pads and repose boots will be positioned to assist in reducing heels and elbows pressures.

For local anaesthetic femoral cases groin area will be previously shaved on the ward, then exposed and cleaned with Chloraprep stick by the scrub nurse prior the procedure.

The patient is covered with a windowed drape at the pelvis level to maintain the groin exposed and femoral access to start the procedure is gained by the Operator.

If general anaesthetic is required then a full anaesthetic team and equipment will also be required.

For surgical access procedures the surgical team will provide the equipment they need.

Monitoring:

The patient will be monitored as below throughout the procedure:

Type of monitoring	Frequency of monitoring
BP	Continuously/invasive throughout procedure
O2 Saturation	Continuously throughout procedure
ECG	Continuously throughout procedure
TEMPERATURE	Not routinely for LA continuously for GA
вм	As required
ACT	As directed by the operator. The team should prompt
	the operator at 30 minutes if not checked.

The Electrophysiologist will print out a report at the end of the case.

Prosthesis verification:

Stock levels within the cath lab should be maintained such that all standard equipment for undertaking coronary angiography and percutaneous coronary intervention is available on request from the operator. Stock control is undertaken via the stock management system within the lab. Any shortages will be identified and alternatives provided.

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester MHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 9 of 33 Version: 2

- Operator/valve loader asks for the relevant equipment and the lab staff will repeat the request verbally.
- The lab staff locates the equipment and offers it, packaged, for the operator to check.
- Primary operator confirms verbally that the packaged item is the intended item for use.
- Packaging opened and equipment placed on the operator trolley.
- Immediately before using any equipment the operator checks visually that it is the intended equipment.
- Operator observes fluoroscopic imaging before deploying any equipment if this is a standard part of the procedure.

After deployment the device stickers are placed in the notes and the theatre/Cardiac Catheter Lab register and scanned onto the stock control system.

Prevention of retained Foreign Objects:

Procedures will be adhered to within the Management of Surgical Swabs, Instruments, Needles and Accountable Items policy (2018)

- A count of all sharps used during the procedure must be documented on the accountable items record sheet. This must be completed at the start of the case and maintained throughout, adding any further items to the count.
- This count must be completed by a scrubbed practitioner and another member of the cath lab team.
- No waste must leave the room during the case until the final count has been made.
 At the end of the case the count must be repeated and checked against the accountable items record. If there are any discrepancies the waste bags will be searched and the missing item must be found before the patient leaves the room.
- The operator must sign to verify all guidewires are intact at the end of the procedure. In addition to
 guidewires, catheters, balloons and delivery devices should be checked routinely by the operator to
 ensure their integrity. If there is any doubt as to the integrity of a guidewire or any piece of
 equipment this should be raised immediately and x-ray screening implemented as appropriate.

Radiography:

All procedures are undertaken with compliance with IRR 17, IR(ME)R 17 and Local Rules. Cardiology IRMER procedures are in place as per IRMER legislation. IRMER training relevant to each role is undertaken at induction and audited.

Sign Out:

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
	Neview date. August 2024
Glenfield Hospital, Angiocatheter Suite	Page 10 of 33 Version: 2

The Sign Out must be performed for all patients who have undergone an interventional procedure before leaving the procedural room.

- Team members who are present at the end of the procedure should not leave the room until this is completed and verified as correct. (Any member of staff leaving the case before it is completed must handover to an equivalent member of staff).
- The nominated Healthcare professional leading time out will request that all the team is present and ask the team to 'stop and pause'.
- The set questions on the designated section of the Checklist are then directed to the appropriate team member/s, who will verbally respond to the questions being asked.
- Implant/device insertion logs and securing of stickers must be confirmed.
- The procedure will be documented either as a written summary in the TAVI pathway booklet or with an appropriate printed electronic procedural summary filed in the patient notes (or attached to the TAVI pathway).
- Finally prior to transfer to the recovery/discharge area the team will review any key plans or concerns for the handover.
- The procedure nurse must complete adequate patient handover to the recovery/discharge area.

The 'Sign Out' sheet is then signed by a registered healthcare professional and retained in the patient's notes as evidence.

Handover:

Specific details for handover to the recovery and subsequently ward staff required are as follows:

- If an increased level of post procedure monitoring and / or higher dependency area other than CCU is required this will be clearly documented.
- Plan for any temporary pacing if required.
- The access device (i.e. Femoral Arterial Sheath or Radial Band) removal instructions and removal time will be clearly documented.
- Any recommended changes to current medication will be documented.
- All medication administered or commenced during the procedure will be handed over to the receiving nurse with an infusion chart as required.

Team Debrief:

A team debrief should occur at the end of all procedure sessions as per WHO checklist which should include:

- The purpose of de-brief is to discuss the sessions' list and identify what went well and what did not.
- The area used should be quiet and free from interruptions.
- The brief may be led by any designated member of the team.

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester MHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 11 of 33 Version: 2

- Any problems with equipment identified and the plan for rectification confirmed. Any long term problem identified to the co-ordinator and the appropriate team
- Identify areas for improvement and escalate to senior team with plan for any change required.

Post-procedural aftercare:

- The patient will be transferred to the Coronary Care Unit for close observation, especially of the cardiac rhythm and femoral access sites.
- Aftercare of the patient is formally documented (specific procedural routine aftercare sheets are stapled in the procedure booklet) with any additional specific aftercare instructions documented in the 'specific aftercare instructions' section in the procedure booklet.
- The patient will be formally handed over to the CCU clinical team.

Discharge:

- The patient will be formally handed back to the clinical team with a documented handover back to ward team for inpatients/patients to be recovered on a ward;
- A discharge letter should be completed using the ICE system and sent home with the patient for patients recovered in the department.

Governance and Audit:

Safety incidents in this area may include;

- Wrong site
- Retained foreign object post-procedure
- · Wrong device

All incidents and near misses will be reported on Datix and appropriate actions taken.

This document will be audited periodically and will be reviewed alongside any changes to the service and practice. The service is under regular review at the Mortality and Morbidity audit meetings.

Regular IRMER compliance audits are undertaken.

Training:

- Angiocatheter Suite Nursing competencies
- Access and knowledge of massive haemorrhage protocol
- Scrub training protocol / procedures (when implemented)
- IRMER relevant training

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 12 of 33 Version: 2

- Helm mandatory training
- · Equipment competency training

Documentation:

All documentation from admission to discharge should be recorded on the standard UHL related admission documents including

- Transcatheter Aortic Valve Implantation Pathway
- Angiocatheter Suite specific UHL Safer Surgery checklist
- Patient property disclaimer
- NHS consent form
- UHL Bed rail risk assessment (if required)
- UHL Falls risk assessment (if required)
- UHL Adult in patient medication record / EPMA available

In addition to this patient procedure details will be recorded onto the DCS Intellect data management system PATS (This is the BCIS database that operators and radiographers fill out separately)

References to other standards, alerts and procedures:

National Safety Standards for Invasive Procedures, NHS England 2015:

 $\frac{https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf}{}$

UHL Safer Surgery Policy: B40/2010

UHL Sedation Policy: Safety and Sedation of Patients Undergoing Diagnostic and Therapeutic Procedures B10/2005

UHL Consent to Treatment or Examination Policy A16/2002

UHL Delegated Consent Policy B10/2013

UHL Guideline: Anticoagulant Bridging Therapy for Elective Surgery and Procedures B30/2016

Surgical Swabs, Instruments, Needles and Accountable Items UHL Policy B35/2007

Sedation UHL Policy B10/2005

UHL Cardiology Guideline C268/2016

UHL Policy on Surgical Safety Standards for Invasive Procedures B31/2016

Ionising Radiation Safety UHL Policy B26/2019

The Ionising Radiation (Medical Exposure) Regulations 2017

The Ionising Radiation Regulations 2017

Further References

Cath Lab Local Rules

Cardiology IRMER procedures

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/20	21
Trust Reference Number: C64/2019	Revision date: Augu	st 2021
University Hospitals of Leicester NHS		
	Review date: Augus	t 2024
Glenfield Hospital, Angiocatheter Suite	Page 13 of 33	Version: 2

Appendix 1: Cath Lab Team Brief / Debrief

	cklist			l in t								ster Trust:		Lab:
cases, led b	y the the cy theatre transfer	the list to dis atre team le e –full hando ring registra	ader. over to	'	 □ All team members have introduced themselves by □ Issues resolved from last debrief. □ Anaesthetic machine & drugs checked and ready. □ Any latex allergies or infection risk. □ Confirm list order. □ Dosimetery for all staff. 					y. CT MD Date:				Started:
								Team Input						Anaesthetic Input
Patient nam Number and Procedure		orrect Ward		ment lable	Essential Imaging checked & available	Outsta tests /		Procedure concerns / requirements	Implants / prostheses checked & available	Antibiotics required	Blood Products required	Post proc		Anaesthetic plan: Patient specific concerns
1.														
2.														
3.														
4.														
5.														
Staff pres	ent:						T	eam Signature	:	Print Nam	e:		Des	ignation:
□ Nurse				Con C	ardiologist			-						-
□ HCA/	CIA		_		naesthetist									
	Practition	ner	_		e Anaesthetist					Date:			Tim	n-
□ ODP			_	Rep						Date.			""	e.
□ Stude	nt		_		grapher						/ /			
☐ Traine	e Cardiol	ogist	_		ac Physiologist									

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 14 of 33 Version: 2

		am De-Brief I in the Cath Lab Bri			Jniversity Hosp	HS oitals	Cath L	ab:
			<u> </u>			S Trust	Consu	Itant:
	debrief performed			No □	Caring at its	best		
	ues arising that need to is Debrief Action Log c		Yes 🗆	No □	CTAN			
	p the Line' issues recor				21(1)	,	Time S	tarted:
					THE LIN	E		
Issue		Action Required		Responsible	Person	Due Da	ate	Completed?
Achievem	ents and what went w	ell?		Could we hav	e made this list more	producti	ve?	
Staff pres	ent:		Team Signat	ture:	Print Name:		Design	nation:
☐ Nurse	•	Con Cardiologist					•	
☐ HCA/	CLA 📮	Con Anaesthetist						
□ Scrub	Practitioner	Trainee Anaesthetist			Date:		Time:	
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☐ Stude	nt 📮	Radiographer			' '			

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Trainee Cardiologist

Cardiac Physiologist

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 15 of 33 Version: 2

Appendix 2: Cath Lab Safe Surgery Checklist

TO A THE NET TO SERVICE A SERVICE AS A SERVI	Cardiac Catheter Department. Safer Procedure Checklist	University Hospitals of Leicester NHS Trust Connect its best
Date:	Procedure:	Caring at its best
SIGN IN	TIME OUT	SIGN OUT
Prior to any cardiac intervention the patient should verbally confirm their identity and planned procedure against wristband and consent form.	After positioning and before skin incision the Cardiologist, Anaesthetist and Cath Lab team members should verbally confirm with reference to the consent form, and wristband;	Before any member of the team leaves the operating theatre, and not before completion of the first surgical dosing count, the team should verbally confirm:
☐ Confirm patient's name, date of birth and Hospital number	☐ Confirm patient name, Hospital number, date of birth	☐ What procedure have you performed and is it correctly recorded
☐ Confirm procedure and site with patient ☐ Confirm valid consent form matches identity and expected procedure	□ Procedure, site and position □ Access planned □ DOACs / Anticoagulation	☐ The count is correct for all instruments, swabs, throat packs, sharps and accountable items
□ Required implants / instruments available □ Yes □ X-ray equipment working □ Yes □ N/A	Known allergy Yes No Is patient for CPR? Yes No	☐ Any equipment issues identified ☐ All cannulae and extensions have been flushed / removed and / Clamped
☐ Blood results available ☐ Yes ☐ No GENERAL ANAESTHETIC CHECKS N/A ■	Operator ☐ Special equipment requirements ☐ N/A ☐ Yes ☐ Expected duration ☐ Concerns or potential critical events	Key concerns for recovery and postoperative management, including if higher level of care required
☐ Anticipated difficulty airway or aspiration risk	Nurse	☐ Issues for de-brief noted
☐ Equipment / assistance available ☐ Anticipated blood loss >500ml (>7ml/kg in a child) ☐ Blood products available if needed	Sterility of instruments confirmed Surgical site care bundle Antibiotic prophylaxis given Patient Warming NVA Yes	☐ Implant device / stent recorded
☐ Use of cell salvage considered	Glycaemic control	
Read out by: (PRINT) Signed:	Hair removal with dippers N/A Yes Essential imaging displayed or reviewed N/A Yes Heparin / VTE discussed Anaesthetist N/A	
	Anaesthetist □N/A □ Patient's ASA status	
Staff present:	Patient specific concerns or serious comorbidity	
HCA / CLA	INTRA-PROCEDURAL PAUSES N/A ■ □ Prosthetic check ■ Cardiologist and team member confirm correct implant and expiry date and details entered in the patient record	
☐ Con Cardiologist ☐ Other ☐ Con Anaesthetist	Read out by: (PRINT)	Read out by: (PRINT)
	Signed:	Signed:
		PCI Catheter Lab. Safer Surgery 6/21

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 16 of 33 Version: 2

Appendix 3: TAVI Count Sheet

	TA	VI	
Please Affix Patient Label Here	Date:		Please Affix Pack Label(s) Here
	Time:		, ,
	Lab:		

Angio Pack / Valve Pack						
Description	Pre Op	Additional				
Forceps Artery Mosquito Curved						
Scissors Sharp / Blunt 13cm						
Orange Hypodermic Needle						
Green Hypodermic Needle						
Pink Kimal Needle						
Filter Needle						
Scalpel No.15						
IV Spike						
Swab Gauze 20 x 10cm (5+5+5+5)						
Red Tags (1+1+1+1)						
Forceps Artery Mosquito Straight (2)						
Spenser Wells Forceps						
Scissors (Pointed)						

Add	itional Ite	ems		
Description	Additional			
Blunt Introducer Needle(s)				
Suture(s)				
Extra Swabs				
Extra Red Tag(s)				
Proglide(s)				
Stylet				
	Pre Op		Post Op	•
Checker 1	·		·	
Checker 2				

Title: Transcatheter Aortic Valve Implantation (TAVI) SOP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 17 of 33 Version: 2

Appendix 4: Pathway of Care: Aortic Trans catheter (Percutaneous) Valve Implantation

PATHWAY OF CARE Aortic Transcatheter (Percutaneous) Valve Implantation

Referral Details

Referring Centre
Date Referred
Date of Admission
Date of Procedure
Type of Procedure

NDARD OPERAT	ING PROCEDU	RE (SOP)			Issue date: 06/	08/2021
Reference Numb	Revision date:	Revision date: August 2021				
ersity Hospitals	of Leicester NHS Trust	5			Review date: A	ugust 2024
field Hospital, Ang	giocatheter Suite				Page 18 of 33	Version:
Valve Clinic Echo				Date		
AV	Root		MV		LV	
Pa Systolic >60m	mHg □Yes	□ No		☐ Not measured	☐ Unknown	
Aortio Valve Peak Gradient	mmHg	Aortio valv	e area	cm ²	Aortio Annular diameter	mm
Aortic Annular Measurement Me	□ TTE	□ TOE □ Other		□ CT □ Unknown	□ MRI	
Aortic Valve Path	ology 🗆 Stenosis	□ Regu	rgitation	Unknown		
Aortic Valve Aetic	logy Congenital	☐ Degeneration		☐ Rheumatic ☐ Other	☐ Bioprosthetic ☐ Unknown	
Extensive Calcific Ascending Aorta	ation of	□Yes	□ No	□ Unknown		
LV Function	☐ Good EF ≥	50% ☐ Fair EF	30-49%	☐ Poor EF <30%	☐ Not measured	Unknown
Angiogram				Date		
CORS	AO		IFA			
Coronary	☐ No vessel with >50% d ☐ Two vessels with >50% stenosis ☐ Not investigated			essel with >50% dian vessels with >50% d		
Left Main Stem Disease	□ No LMS disease / LMS diameter stenosis	8 disease £50%	□ LMS >	50% diameter steno	sis 🗆 Unknown	
Previous MI and I	nterval No	previous MI	□ MI < 6		8 – 24 hours > 90 days	
between procedu	TO ATTO TACK THE LE MI	1 – 30 days	LI MI SI	- so days Li Mi	- 30 days	

☐ Cardiogenic Shock immediately pre-procedure

□ IV inotropes immediately pre-procedure

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/20	21
Trust Reference Number: C64/2019	Revision date: Augu	st 2021
University Hospitals of Leicester NHS		
	Review date: August	t 2024
Glenfield Hospital, Angiocatheter Suite	Page 19 of 33	Version: 2

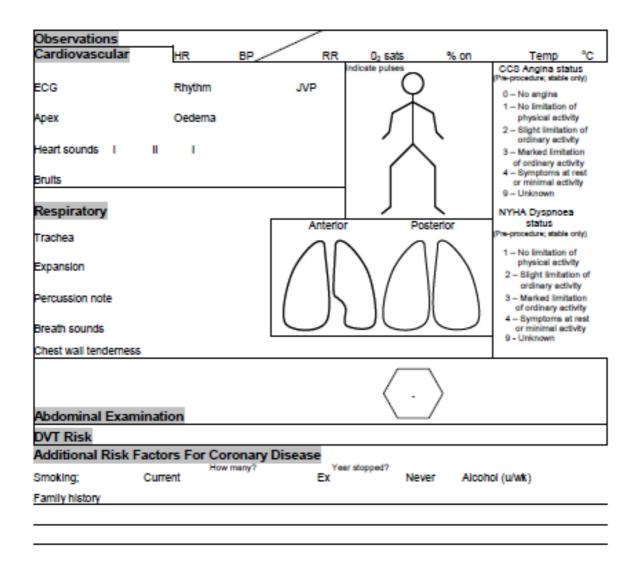
Extracardiac Arteriopathy	□ No	□ Yes	Unknown	
			•	
	□ Conservative	re (continue medical the	rapy)	
MDT decision	☐ Transcathe	ter Aortic Valve Implant	ation	
	☐ Surgical Ac	rtic Valve Operation		
Expected Procedure Expected Valve	□ Transap	Ical	□ Percutaneous	
Expected Valve	□ Core		□ Edwards	
Euro Score		Lee Score		
Comments				
			• • • • • • • • • • • • • • • • • • • •	
SIGNATURE:		DATE:	TIME:	

STANDARD OPERATING PROCEDURE (SOP)	lssue date: 06/08	/2021
Trust Reference Number: C64/2019	Revision date: Au	ıgust 2021
University Hospitals of Leicester NHS		
NHS Trust	Review date: Aug	just 2024
Glenfield Hospital, Angiocatheter Suite	Page 20 of 33	Version: 2

- 1

Modical Even	nination							
Medical Exam				П	Dact Proced	lural / Surgica	d History	
Past Medical H	□ Not diabetic	D Die	betes - diet		Specifically	□ No	□ CABG	
Diabetes	☐ Diabetes – Oral med		ibetes - diet ibetes - insulin	—		☐ Valve operation	☐ Unknown	
UTAL-VILLE S		_			Previous cardiac	☐ Operation requirir		
	☐ Newly diagnosed diabe		Unknown	_	surgery	pericardium		
	☐ Native RF	□ Un	known	41	41	□ No		
Renal function	☐ Acute RF: dialysis	□ Ch	Chronic RF: dialysis		Previous Aortic	 Yes, Ao velvulopi as part of a stage 	esty but NOT ed procedure	
	☐ Functioning transplant	oning transplant			Valve percutaneous	☐ Yes, staged Ao v		
	□ No □ Asthme		Unknown		procedure	part of this proce	dure	
Pulmonary disease	□ COPD / Emphysema			╗		☐ Yes previous	Unknown	
	□ No □ TIA / RING	n Hille	known	-		TAVI No	Unknown	
H _s of neurological	CVA full recovery	_	A residual deficit	\dashv	Previous PCI	Yes, but NOT as		
disease	☐ Other history of neurolo			-11		Yes, as part of th		
Drug History								

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021		
Trust Reference Number: C64/2019	Revision date: August 2021		
University Hospitals of Leicester NHS			
NHS Trust	Review date: August 2024		
Glenfield Hospital, Angiocatheter Suite	Page 21 of 33 Version: 2		



Height		Weight		BMI		
Blood Results		Urea	Cr	Na*	K*	
	BNP	CRP	FBC	Coag	LFT	
	Chol	Trop I	С	ross matched &	Saved Y/N	Date

SIGNATURE:	DATE:	TIME:
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STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 22 of 33 Version: 2

Pre Procedure Check List		Signature	
Patient fasted (food - 6 hours, cle	ar fluid - 2 hours)		
Consent form signed	,	[•
18 Guage Intravenous cannula in	place and patent	[]
ID bracelet in place		[]
Loaded with Clopidogrei (300mg)	and Aspirin (300mg)	[]
Administer pre-med if required		[]
Physical preparation completed		[]
CHECKLIST			
Consent form () []</td <td></td> <td>Language spoken</td> <td></td>		Language spoken	
Current MRSA status (give date o	f last swabs taken):		
Seen by anaesthetist \	/ES / NO	Urinary catheter:	YES / NO
Pacemaker:	/ES / NO	Hearing Ald:	YES / NO
Dentures removed:	/ES / NO	Crowns noted:	YES / NO
Make up / nall vamish removed: \	/ES / NO / NA	Prosthesis	
Jewellery taped / removed:	/ES / NO / NA	Waterlow score	
BPSp02	RR		
X-rays, notes, ECG with patient (() []	Allergles:	
Height Weight .			
Blood results in notes () (U/E, FBC, Group and Save etc)</td <td>[]</td> <td>INR:</td> <td></td>	[]	INR:	
(,,,,		Infusion(s)	
Any other relevant information:			
Daliant confirms that that the con-	and assessments of according	and to	
Patient confirms that that they are Name signature		opnate) ation of person completing t	
rvaine signature	- uesigna	ation of person completing t	uno Grecanot,

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 23 of 33 Version: 2

Catheter lab documentation	Date		Time			
1 st Operator			Anaesthetis	t		_
2 nd Operator			Assistan	t		
Procedure (state number & loca Operator:	tion of sheaths)			Pre-operative	heart rhythm	
орению.				☐ Atrial fibrillatio	n / firster	
				☐ 1 st degree hea		
				□ RBBB	III DIDUK	
				□ LB8B		
				☐ Complete hea	rt Noek	
				☐ Paced rhythm		
				_	chycardia or fibrille	rtion
				☐ Other abnorm	•	
				☐ Other abnorm		
				□ Unknown		
Procedure data						
Proctored case	□ No	☐ Yes				
10000120002						
Pre procedural imaging	□ None	□ TTE	□ TOE	□ Other		
Procedure urgency	☐ Elective	☐ Urgent	☐ Emergency	□ Salvage		
Aortic Balloon Valvuloplasty	☐ Not done	☐ Completed	☐ Failed			
Anaesthesia	□None	☐ Sedation	Regional	☐ General		
Diameter of largest balloon		_mm				
Delivery approach	☐ Fernoral percutaneous	☐ Fernoral surgical	☐ Axillery	☐ Subclevien	☐ Transapical	□ Other
Sheath size (if percutaneous)		French				
Circulatory support	□ No	☐ Elective	☐ Emergency	Unknown		
Catheter lab' details cont' Valve details	Manufacturer Serial number		Model Size			

Authors: J Steele

IDARD OPERATING F Reference Number: C		<i>50. j</i>				date: 06/08 ion date: Au	
ersity Hospitals of Lei					1.0710	21. 20.01710	. J J .
,	NHS Trust				Revie	w date: Aug	
ield Hospital, Angiocat	heter Suite				Page 2	24 of 33	Version:
		J					
Device failure	□ No Fel	lure 🗆 Probet	dy jatronanie	☐ Probably	v intrinsie	□ Unknown	
Vascular closure technique							
Valve successfully deploye		pressure	□ Surgical ci	osure	☐ Device clos	ure	
		□ No	Unknown		Dilleteres		
Aortic regurgitation (by ech		□ Mild	□ Moderate	□ Severe	□ Unknown	Unknown	
Aortic regurgitation (by ang Death						LI ORKROWN	
	□ No	□ Yes	Unknown				
Myocardial Infarction	□ No	□ Yes	Unknown		- - - - - - - - - -		
Tamponade	□ No			intervention	□ Yes – requ	ring percutaneou	s intervention
Major vascular injury	□ No	☐ Yes	Unknown				
Major apical cannulation complications	□ No	☐ Yes	Unknown				
Ballout PCI	□ No	☐ Yes	Unknown				
New conduction abnormal requiring pacing	ty □ No	☐ Yes	□ Unknown				
	rv □ No	□ Yes	Unknown				
Conversion to valve surger CVA	•						
	□ No	□ Yes	Unknown				
Emergency valve in valve	□ No	□ Yes	Unknown				
Cardiogenic shock	□ No	☐ Yes	Unknown				
Device embolisation	□ No	☐ Yes	Unknown				
AVR Gradient AV	'R areas	Deploy		Device ge	eometry	MV	
		1					

Authors: J Steele

8

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 25 of 33 Version: 2

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Indicate discipline (e.g. medical / nurse / physio for ease of reference)	TAVI notes	Sign/print/ date/time

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 26 of 33 Version: 2

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Indicate discipline (e.g. medical / nurse / physio for ease of reference)	TAVI notes	Sign/print/ dete/time

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Davieno deter August 2004
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Glenfield Hospital, Angiocatheter Suite	Page 27 of 33 Version: 2

Indicate discipline (e.g. medical / nurse / physio for ease of reference)	TAVI notes	Sign/print/ date/time

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 28 of 33 Version: 2

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Indicate discipline		
Indicate discipline (e.g. medical / nurse / physio for ease of reference)	TAVI notes	Sign/print/ date/time

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 29 of 33 Version: 2

Indicate discipline (e.g. medical / nurse / physic for ease of reference)	TAVI notes	Sign/print/ date/5me

NDARD OPERATING PROCE		lssue date: 06/	08/2021
Reference Number: C64/2019		Revision date:	August 202
ersity Hospitals of Leicester NHS Trust		Review date: A	
ield Hospital, Angiocatheter S	uite	Page 30 of 33	Versio
Indicate discipline (e.g. medical / nurse / physio for ease of reference)	TAVI notes		Sign/print/ date/time
Date of discharge or death Discharge destination from	☐ Home ☐ Convalescence	ce Other hospital	

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019 Revision date: August 2021	
University Hospitals of Leicester NHS	
NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 31 of 33 Version: 2

Post Procedural complications Death	□ No	□ Yes	Unknown	
Myocardial Infarction	□ No	□ Yes	Unknown	
CVA	□ No	□ Yes	Unknown	
TIA / RIND	□ No	☐ Yes	Unknown	
Valve in valve implantation	□ No	☐ Yes	Unknown	
Surgical AVR	□ No	☐ Yes	Unknown	
Permanent pacing	□ No			ure therapeutic (including distant past)
	Yes, pre-proced Yes, post-proce		☐ Yes, per-proced ☐ Unknown	ure
Device migration	□ No	☐ Yes	Unknown	
GI Haemorrhage	□ No	☐ Yes	□ Unknown	
Tamponade	□ No	□ Yes	Unknown	
Platelet transfusion	□ No	☐ Yes	□ Unknown	
New haemoflitration or dialysis post-operatively	□ No	□ Yes	Unknown	
Late vascular complications requiring surgery	□ No	□ Yes	Unknown	
Infective endocarditis	□ No	☐ Yes	Unknown	
•		1 year Follow up)	
Life status	☐ Alive	☐ Deed		
If alive: CCS angina status	☐ No angina	☐ No limitation of phy	rsical activity	☐ Slight limitation of ordinary activity
	☐ Marked limitation	n of ordinary physical a	ctivity	Symptoms at rest or minimal activity
	Unknown			
If alive: NYHA dyspnoea status	☐ No limitation of p	physical activity		☐ Slight limitation of ordinary activity
	☐ Marked limitation	n of ordinary physical a	ctivity	☐ Symptoms at rest or minimal activity
	Unknown			
Ma adadus	T. 45	3 year Follow up		
Life status	□ Alive	□ Deed	Unknown	
If alive: CCS angina status	☐ No angina	☐ No limitation of phy	rsical activity	☐ Slight limitation of ordinary activity
	☐ Marked limitation	n of ordinary physical a	ctivity	☐ Symptoms at rest or minimal activity
	☐ Unknown			
If alive: NYHA dyspnoea status	☐ No limitation of ;	physical activity		Slight limitation of ordinary activity
□ Unknown		n of ordinary physical a	ctivity	☐ Symptoms at rest or minimal activity
15				

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS NHS Trust	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 32 of 33 Version: 2

Appendix 5: Pre and post care of a TAVI patient

Pre and Post Procedure Care for a TAVI patient Nursing Care Plan

	Nursing Care Plan for an adult patients who is having a TAVI
Pre-op:	·
1	Patient clerked in by Medical team
2	eMeds/medicine chart completed by the Medical team
3	Blood tests done on the preadmission day including INR by medical staff
4	Check infection status from the preadmission clinic
5	Anticoagulation treatment on hold as instructed by the consultant
Day of the	Procedure:
6	Keep patient NBM for 6 hours prior to the procedure
7	4units blood cross matched and available for the day
8	Venous access(prefer 18G) available and working well for the procedure
9	Give antibiotics instructed by consultant just before transferring to the Cath lab/theatre
10	Patient be ready in hospital gown for the procedure
11	Cath lab/theater check list and TAVI care pathway completed and kept in the nursing folder
12	Print out all the blood results and kept in the medical note
Post-TAVI	
13	Base line Vital signs and repeat every ½ hours for 2 hours and then 1 hourly until consultant review (more frequent if condition dictates).
14	Monitor blood sugar as required post baseline reading.
15	Inspect and palpate the incision site on admission to the ward.
	If there is any sheaths in situ:
	Check clear dressing over the sheath for better detection of bleeding.
	Check appropriate obturator in the sheath to prevent kinking, clotting and bleeding.
16	Baseline ECG required as patient may present with LBBB which may just require observation, or treatment if presenting with symptoms (symptomatic bradycardia).
17	Base line temporary Pacing checks on admission, and repeat at the beginning of each 12 hr shift and repeat if there is any risk of displacement. TPW to remain in situ for approx. 24 hrs or until senior review and instructs removal.
18	Baseline pedal pulses and warmth of feet checked, then hourly until sheaths/lines removed and thereafter minimum twice daily.
19	If patient have a urinary catheter in to be remaining in situ until consultants review/instructs removal (see UHL catheter care pathway).
20	Bed rest maintained until 2 hours post sheath removal/ consultant review

Title: Transcatheter Aurtic valve implantation (TAVI) SUP

Authors: J Steele

STANDARD OPERATING PROCEDURE (SOP)	Issue date: 06/08/2021
Trust Reference Number: C64/2019	Revision date: August 2021
University Hospitals of Leicester NHS	Review date: August 2024
Glenfield Hospital, Angiocatheter Suite	Page 33 of 33 Version: 2

Nursing Care Plan for an adult patients who is having a TAVI		
21 Maintain venous cannula access as per UHL cannula care pathway.		
22	Strict fluid intake and output chart to maintain hydration status.	
23	Care of Femoral Sheaths:-	
20	If temporary femoral access sheaths are in —It may remove after 2 hrs post procedure when return to the ward if there are no post-op complications after review by TAVI team or senior medical team.	
	Femoral sheath removal:	
	 Confirm the removal by the responsible medial team. Make sure vital signs are stable and no chest pain (if patient hypertensive consider antihypertensive medication prior to removal) Check ACT and if it is less than 150 can remove the sheath and if it is above 150 wait ½ - 1 hour and repeat. Apply pressure on the site, usually 10 minutes (depends on the sheath size, 	
	ACT and ease of control on the bleeding)	
	 Make sure two staffs are available while removing the sheath (one to apply pressure and one to administer emergency medication if needed) Make sure Atropine is available and within reach(vasovagal/ bradycardia) Check BP every 3 minute while removing the Sheath and pedal pulse regularly. Apply Gauze dressing and can sit up slightly with legs in straight position. 	
	Leave some gauze with patient to press on incision site if coughing post removal.	
	 Keep Bed rest for 2-4 hrs (varies on sheath size) and can gently mobilise in the absence of bleeding or haematoma formation. Ambulation should be gradual. 	
	Venous sheath Removal:	
	 Confirm the removal by the responsible medial team. 	
	Make sure vital signs are stable and no cardiac arrhythmias.	
	 Apply pressure for usually around 5-10 minutes until bleeding stops. Keep bed rest for 2 hrs afterwards and can gently mobilise in the absence of bleeding or haematoma formation 	
	Apply Gauze dressing on. Femoral Sheath removed Yes/no Date &time: Signature:	
	Femoral Sheath removed Yes/no Date &time: Signature: Venous sheath removed Yes/no Date &time: Signature:	
	render rended reside state. Ognatie.	
	If the venous and arterial sheaths in situ and both need removal: Always remove the Arterial sheath first to reduce the risk of atrioventricular fistulas, haematoma formation and blood loss.	
	Continue to observe the incision site until discharge.	
	All femoral sheaths should be removed in CCU before moved to other ward areas	
\wedge	If there are any complications such as cardiac arrhythmias, bleeding and Renal problems-need urgent medical review.	

Title: Transcatheter Aortic valve implantation (TAVI) SOP

Authors: J Steele