States of Guernsey
Hospital Services

TAVI (Transcatheter Aortal Valve Implantation) commissioning guidelines

This document provides guidance on the local TAVI assessment and tertiary referral pathway for patients who would benefit from this procedure as an alternative when SAVR (Surgical Aortic Valve Replacement) is not possible. The assessment criteria herein must be completed before referral to the tertiary provider can be made by the off-island team.

Lead Professional/Author	Peter Rabey, Medical Director
Working Party Contributing Professionals	Consultant Cardiologist, General Practitioner, Medical Director
Consultation List	Consultant Cardiologists, Medical Specialist Group TAVI MDT lead, University Hospital Southampton General Practitioner, Guernsey Geriatrician, Medical Specialist Group
Version	1
Accepted by Drugs and Therapeutics Committee	Not applicable
Ratified by Peter Rabey	P C Rabey P.G. RASEY Date: 13 September 2018 13/9/18
Ratified by Quality Governance Committee	22 August 2018
Issue Date	18 September 2018
Review Date	17 September 2019

Key words: Transcatheter Aortal Valve Implantation (TAVI), Heart Failure, Aortic Stenosis, Tertiary, Cardiology

Version History

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
1.0	July 2018	Medical Director	PMO - ADC	Draft	New Commissioning Policy

Document Control

TAVI assessment and tertiary referral protocol

This is a controlled document. Therefore, it should always be accessed from the intranet and should not be saved onto local or network drives for use.

While this document may be printed, the electronic version displayed on the HSC intranet and States of Guernsey website is the one that staff should refer to if it is available because it is the most up-to-date version. Any printed copies of this document are not controlled and may become obsolete without notice.

Contents

TAVI assessment and tertiary referral guidelines

1. Introduction

TAVI is a procedure which is performed on patients who have symptoms of advanced aortic stenosis, who for various reasons are physically unable to withstand open heart surgery.

Aortic stenosis is an insidious disease with a long latency period, followed by rapid progression after the appearance of symptoms, resulting in a 50% death rate among untreated patients in the first 2 years after symptoms appear. Aortic stenosis leads to increasing heart failure.

Traditionally, open-heart surgery (SAVR) has been the way to repair or replace aortic valves, and this procedure is currently States-funded in a tertiary specialist centre for Guernsey patients. Approximately 20 SAVR procedures were performed in 2017.

However, on rare occasions, patients present who have unusual reasons to be unsuitable for standard SAVR surgery. In the three years preceding 2018, one patient per annum was approved for TAVI by the HSC Individual Funding Request committee.

This guideline has been developed to make the assessment process fair, complete and transparent, in line with Public Health Policy 1033. It will ensure that, when any individual assessment process concludes that TAVI would be a futile endeavour, the patient can be fully informed as to the reasons for the conclusion.

Studies of patient outcomes since 2011 have shown that a significant percentage of recent TAVI recipients across the UK failed to derive a benefit from TAVI, either dying or displaying a lack of clinical and functional improvement in the first postoperative year. This procedure carries many risks in comparison to traditional (SAVR) surgery, particularly since most candidates will already have advanced pathology. Five year outcomes studies have proven high post-treatment complication rates, thus, the need for a rigorous clinical and holistic assessment prior to surgery.

2. Objectives

- To provide clear guidance on who can refer patients to the tertiary provider.
- To provide clear guidance on which patients may be referred to the tertiary provider.
- To provide information on how referrals must be made to the tertiary service.

3. Target Population

Among the Guernsey population, according to Public Health data, there are approximately 165 individuals aged over 75 who presently (given UK statistics) suffer from heart valve stenosis of various kinds. A subgroup would specifically have aortic stenosis requiring assessment for treatment.

In 2017, approximately 20 Guernsey patients were sent to a UK specialist centre for SAVR (surgical aortic valve replacement), and one patient was deemed inoperable by SAVR and therefore received TAVI.

In 2015-2016, data shows that 21 patients were admitted to PEH with a primary diagnosis of aortic stenosis.

Although most patients with aortic stenosis would likely be in the over-75 age group, it is also possible for younger patients to appear due to rare events such as trauma, previous irradiation, or co-morbidity such as an undisturbable tumour. Age is not a key determining factor in assessing suitability for TAVI.

4. Sources of referral

Patients may be referred to the SAVR/TAVI service in any of the following three ways:

- Patients identified during hospital admission with aortic stenosis. These patients **must** be under the care of one of the Consultant Cardiologists.
- Unstable patients with a confirmed diagnosis of aortic stenosis

attending Cardiologist led outpatient clinics.

- Patients returning from University Hospital Southampton (UHS) or other tertiary centres with a confirmed diagnosis of aortic stenosis.

5. Assessment Pathway

A thorough TAVI assessment needs a holistic whole-person view, with the pros and risks of surgery clearly explained to patients with capacity to understand this discussion. Many candidates will have a history of extensive cardiac treatment, and now are facing tissue deterioration which threatens overall heart function.

STEP 1. Local Clinical Assessment: Local imagery by CT angiogram and Heartflow modelling (if deemed necessary by the cardiologist), read by a cardiac surgeon, is basic. These tests can help determine tissue and functional insufficiency which would preclude any attempt at valve replacement.

STEP 2. Local Holistic Assessment done by an expert (Geriatrician) in multimorbidity who ideally knows the patient, and who can give an opinion on fitness for TAVI and optimisation of medical co-morbidities. There is now substantial data around postoperative risk available from five-year follow up studies.

STEP 3. The standard EUROSCORE 2 system (European Score for Cardiac Operative Risk Evaluation) could be used in Guernsey for assessing 30-day morbidity risk in candidates for TAVI. The logistic EUROSCORE 2 used across European jurisdictions for TAVI eligibility is <18-20% for those with severe aortic stenosis and contraindications for open heart surgery. This scoring system does not consider holistic factors at all.

STEP 4. <u>Evaluation by Southampton MDT for TAVI suitability is the vital next step</u> if the candidate is not eliminated for consideration locally, AND if the candidate is willing to undergo more investigation. This would require imaging files sent via the PACS system, and likely two attendances at Southampton for evaluation by that team. Specialist gated CT scans at Bournemouth might be required by the Southampton assessors.

STEP 5. **Decision re referral for TAVI** – or, refusal on any sensible grounds,

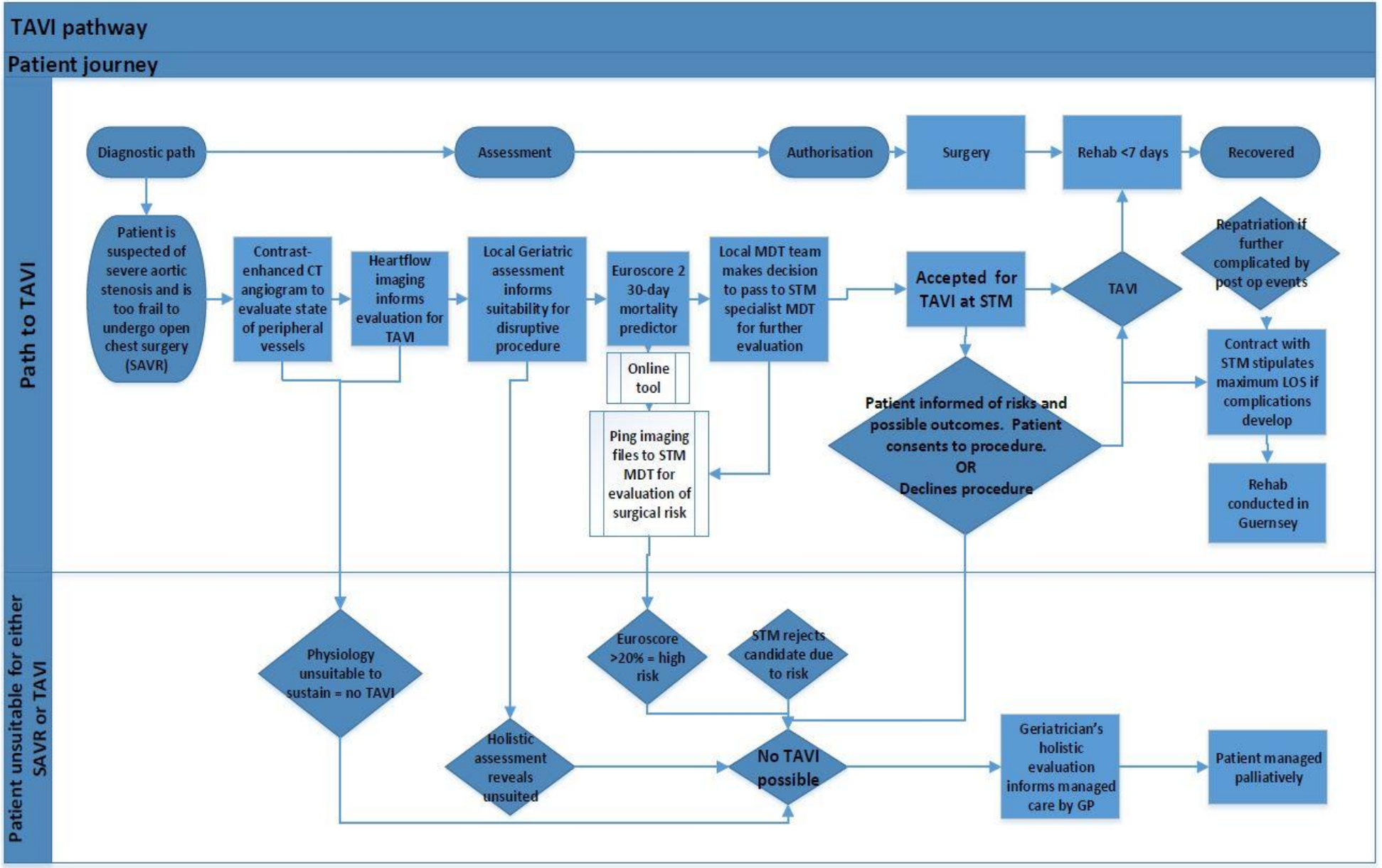
or decision by patient to not proceed.
STEP 6a. **For refusals, immediate referral to geriatrician** with knowledge of the case.

STEP 6b. **For acceptances, referral for TAVI sent to Off-island team**. The referring specialist must include the following in any referral to the Off Island team for TAVI:

- CT angiogram and Heartflow results, interpreted by a cardiac surgeon.
- Geriatric evaluation from a local specialist outlining patient's suitability for the procedure.
- A EUROSCORE 2 assessment of < 18.
- Request for assessment for surgical suitability from Southampton MDT.
- Patient accepts the risks as explained by a Guernsey cardiologist.

6. Patient pathway

A flow chart of the patient pathway is shown on the next page.


TAVI pathway
Patient journey
Path to TAVI
Diagnostic path
Assessment
Authorisation
Surgery
Rehab <7 days
Recovered
Patient is suspected of severe aortic stenosis and is too frail to undergo open chest surgery (SAVR)
Contrast-enhanced CT angiogram to evaluate state of peripheral vessels
Heartflow imaging informs evaluation for TAVI
Local Geriatric assessment informs suitability for disruptive procedure
Euroscore 2 30-day mortality predictor
Online tool
Ping imaging files to STM MDT for evaluation of surgical risk
Local MDT team makes decision to pass to STM specialist MDT for further evaluation
Accepted for TAVI at STM
Patient informed of risks and possible outcomes. Patient consents to procedure.
OR
Declines procedure
TAVI
Repatriation if further complicated by post op events
Contract with STM stipulates maximum LOS if complications develop
Rehab conducted in Guernsey
Patient unsuitable for either SAVR or TAVI
Physiology unsuitable to sustain = no TAVI
Euroscore >20% = high risk
STM rejects candidate due to risk
Holistic assessment reveals unsuited
No TAVI possible
Geriatrician's holistic evaluation informs managed care by GP
Patient managed palliatively

7. Tertiary referrals

Once accepted, these patients will be contacted by telephone (off-island team) to support the details of their transfer to Southampton. Rare emergency cases could necessitate air ambulance transport. All relevant files, both clinical and digital, will be sent by the Cardiology team to Southampton prior to the patient's travel.

The Southampton MDT will then embark on their own patient assessment for surgical suitability, and will contact the referring cardiologist if the case needs further discussion.

If accepted for the surgical list, the patient will then receive TAVI as a matter of urgency in most cases.

8. Distribution

This Guideline will be placed on PoliPlus by the Clinical Audit and Quality Manager. Paper copies will be made available to staff who do not have access to the Intranet by their managers. Staff will be informed of the inclusion of the policy on PoliPlus by e-mailed circular. Primary Care will be sent paper copies of the document.

9. Training

Formal training in relation to this guideline is not required. However, it is the responsibility of all Staff involved in the care of patients with aortic stenosis to ensure that they have read this guideline and that they are familiar with their role in relation to the referral of patients to the tertiary service.

10. Responsibility

The Medical Director and the working party are responsible for the clinical and technical content of the document. The Cardiologists are responsible for implementing this policy along with the off island team, to ensure staff adhere to the guidelines outlined here.

11. Accountability

The Cardiologists are accountable to the Medical Director for ensuring these guidelines are implemented throughout HSC services. The Clinical Nurse Medical Director is accountable for the clinical and technical content of this document.

The Clinical Guidelines Committee has reviewed the document for compliance with the procedures outlined in the HSC policy *Policies and procedures, Guidelines and Protocols* and has provided the author with advice.

12. Compliance

The Off island team will audit the number of referrals received to the tertiary service and be responsible for ensuring that the referral process set out in this policy is adhered to. Number of referrals will be collated on a monthly basis and if appropriate the inclusion criteria for the service will be reviewed again in the future.

Key performance indicators (KPIs) will be measured at 12 months to ensure this guideline is relevant and working effectively. These KPIs include that every inpatient returned to the island post recovery will be offered an outpatient appointment within 10 days of referral from tertiary centres.

A staff signature sheet is included in Appendix B so that staff can sign to say they have read and understood this policy. Service managers should retain an up-to-date copy of this sheet for their area.

13. Review

A review of this policy will take place after at one year by the Medical Director in conjunction with the Consultant Cardiologists. The author and the Clinical Audit and Quality Manager will keep an editable electronic copy of the ratified document on file. Further reviews will take place at least every three years or sooner if required.

14. Removal

This policy will be retained on PoliPlus until such time as the Quality Governance Committee has approved its replacement. There was no preceding policy for TAVI on PoliPlus and so no historical policy documentation exists.

15. Effective Date

This “TAVI assessment criteria and tertiary referral protocol” was ratified by the Quality Governance Committee on 22/08/2018 and comes into effect on the issue date shown on the title page.

TAVI tertiary Referral – Off island

Inclusion criteria Adult with confirmed identification of aortic stenosis with ineligibility for SAVR

Please return this form to the Off island Department

Use address label if available Patients Name: Address: Telephone: Unit No: DOB:	Date of referral: Name of Referrer: **If in-patient:** Ward: Anticipated discharge date:

Standard off-island referral letter from MSG [Cardiology] should include:

1. Local clinical assessments completed

CT coronary angiogram
Heartflow FFRCT (optional)
Relevant clinical observations that preclude SAVR
Past medical history/co-morbidities
Current medications

2. Local geriatric assessment completed

3. Euroscore 2 result [must be <18] available at:
http://www.euroscore.org/calc.html

Staff Signatures Assurance Form

To be kept by the ward, unit or departmental manager

TAVI tertiary referral guidelines

Ward/Department: Cardiology

I have read and understood the above document.

Name	Signature	Date