States of Guernsey
Hospital Services

TAVI (Transcatheter Aortic Valve Implantation) assessment and tertiary referral protocol

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.

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Consultation List	Medical Director, Client Team, Medical Specialist Group
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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.

Version History

Version Number	Date	Person responsible	Prepared by	Status	Reason for Issue
2	Apr 2022	Medical Director	Public health Advisor	Approved	Reviewed. Index number changed to G1027(a). Minor amendments made to original text. Insert reference to the TAVI treatment policy (G1027 (b)).
1	July 2018	Medical Director	PMO - ADC	Adopted	Referral protocol for a new

Contents

TAVI assessment and tertiary referral protocol

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.

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.

From 2018 to 2020, 65 SAVR procedures were performed as well as 11 TAVI procedures.

This protocol 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 a tumour which should not be disturbed. 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

An assessment for intervention for aortic stenosis requires comprehensive balancing of the risks of surgical AVR versus TAVI. This involves a holistic whole-person view, with the pros and risks of surgery clearly explained to patients with capacity to understand this discussion performed by the UHS MDT team. 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 assessment by MSG cardiologist

STEP 2. If deemed fit for SAVR or TAVI then referred to UHS for MDT assessment. CTCA imaging will be required for all at this stage. Those not suitable for SAVR may later require CT aorta TAVI imaging.

STEP 3. UHS MDT assessment

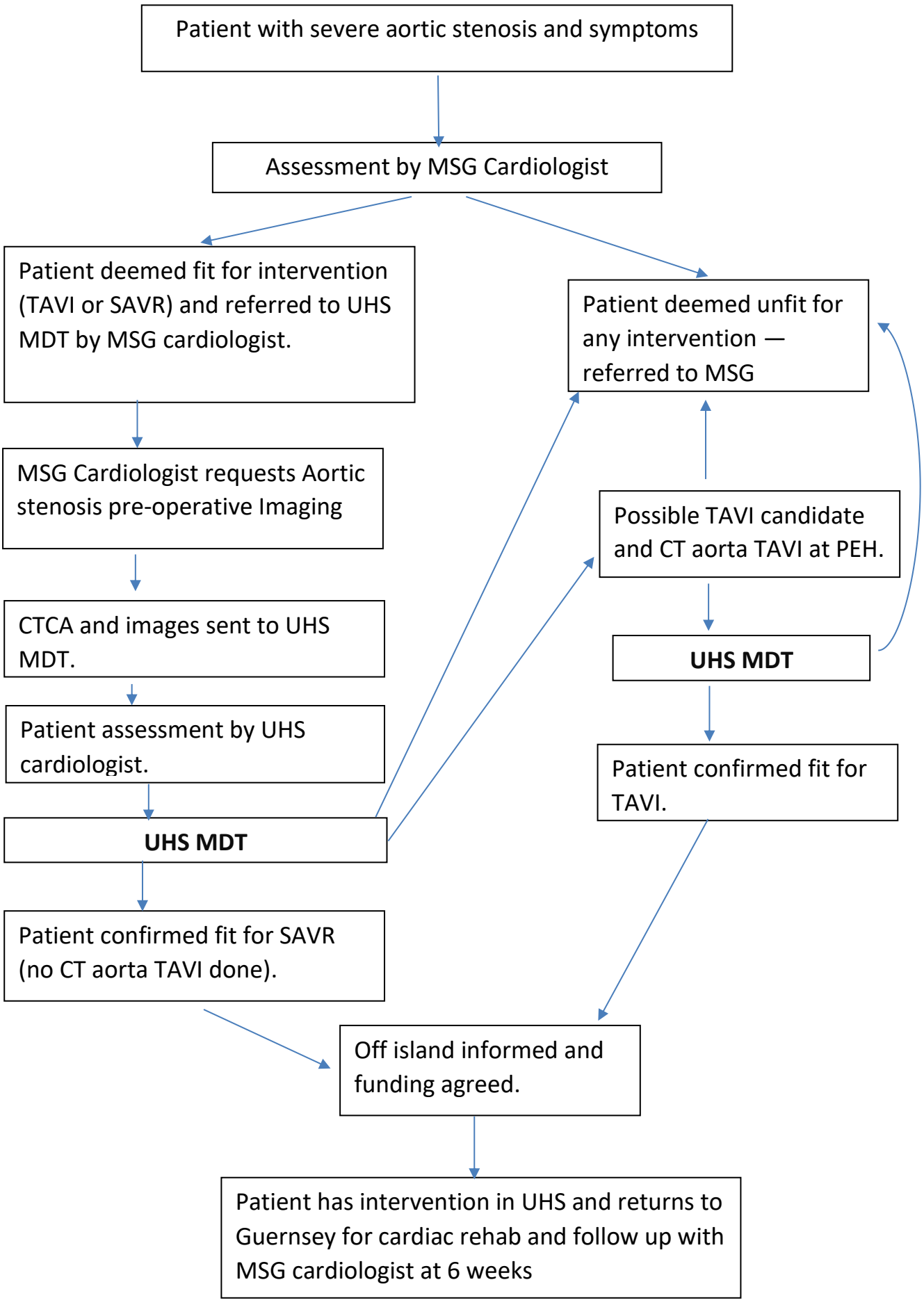
STEP 4. Patients either deemed

a. Fit for SAVR
b. Possible TAVI Case
c. Unfit for any intervention

STEP 5. Patients deemed possible TAVI cases require the CT aorta TAVI in PEH with subsequent second assessment in UHS MDT.

STEP 6. Both UHS agreed SAVR and TAVI cases are then finally assessed by off-island team where funding is agreed

STEP 7. Patient unfit for intervention referred to geriatrician at MSG or PEH palliative care


Patient with severe aortic stenosis and symptoms
Assessment by MSG Cardiologist
Patient deemed fit for intervention (TAVI or SAVR) and referred to UHS MDT by MSG cardiologist.
Patient deemed unfit for any intervention — referred to MSG
MSG Cardiologist requests Aortic stenosis pre-operative Imaging
Possible TAVI candidate and CT aorta TAVI at PEH.
CTCA and images sent to UHS MDT.
UHS MDT
Patient assessment by UHS cardiologist.
Patient confirmed fit for TAVI.
UHS MDT
Patient confirmed fit for SAVR (no CT aorta TAVI done).
Off island informed and funding agreed.
Patient has intervention in UHS and returns to Guernsey for cardiac rehab and follow up with MSG cardiologist at 6 weeks

6. 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.

UK providers are expected to treat patients in line with NHS England's commissioning policy for TAVI, including submitted data to the UK TAVI register as activity is based in the UK.

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

7. Distribution

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

8. Training

Formal training in relation to this protocol 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 protocol and that they are familiar with their role in relation to the referral of patients to the tertiary service.

9. 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 protocol along with the Off-island Team, to ensure staff adhere to the protocol.

10. Accountability

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

11. 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 protocol 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 protocol 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 protocol. Service managers should retain an up-to-date copy of this sheet for their area.

12. Review

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

13. Removal

This protocol will be retained on PoliPlus until such time as the Quality Governance Committee has approved its replacement.

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 inpatient:** Ward: Anticipated discharge date:
<u>Standard off-island referral letter from MSG [Cardiology] should include:</u> <u>1. Local clinical assessments completed</u> CT coronary angiogram Relevant clinical observations that preclude SAVR Past medical history/co-morbidities Current medications	

Staff Signatures Assurance Form

To be kept by the ward, unit or departmental manager

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Ward/Department: Cardiology

I have read and understood the above document.

Name	Signature	Date