Meeting Date	**28 January 2021**	**Agenda Item**	**2.3**
Report Title	Transcutaneous aortic valve insertion (TAVI) – Progress Report		
Report Author	Dr Richard Evans, Executive Medical Director		
Report Sponsor	Dr Richard Evans, Executive Medical Director		
Presented by	Dr Richard Evans, Executive Medical Director		
Freedom of Information	Open		
Purpose of the Report	To report the progress made in treating the patients on the TAVI waiting list and to give assurance regarding the effectiveness of the clinical governance oversight in response to the Royal College of Physicians' review of the service.		
Key Issues	• The report summarises the findings of the Royal College of Physicians' (RCP) review of the service and the actions taken in response to improve outcomes • Monitoring demonstrates strong compliance with standards of care • A further review of casenotes has been undertaken by the RCP and their report is awaited.		

Specific Action Required ***(please choose one only)***	**Information**	**Discussion**	**Assurance**	**Approval**
	☐	☐	☒	☐

Recommendations	Members are asked to: • **AGREE** the effectiveness of the changes implemented and that these are evidenced against best practice standards. • **AGREE** to continued oversight of the service in order to ensure the changes made are embedded and sustainable • **AGREE** that the response to the further casenote review will be overseen by the Quality and Safety Committee • **NOTE** that the costs of the improvements to the service are accounted for within the financial forecast.

TRANSCUTANEOUS AORTIC VALVE INSERTION UPDATE

1. INTRODUCTION

This paper provides an update on progress on transcutaneous aortic valve insertion (TAVI) focussing on the progress made in treating the patients on the waiting list, and an update on the external review of the service by the Royal College of Physicians (RCP).

2. BACKGROUND

TAVI is a procedure used in people who have severe aortic stenosis as an alternative to conventional 'open' surgery for replacing the aortic valve. TAVI may be the procedure of choice for patients in whom conventional surgery is precluded due to the clinical risk associated with multiple co-morbidities or frailty.

In 2018 it became apparent that a number of patients had died while on the waiting list for TAVI. Given the mortality associated with severe aortic stenosis, there was concern that failure to address a growing waiting list was material in causing harm to patients. In response, the Health Board convened an executive-led 'Gold Command' group to oversee improvement actions.

3. EXTERNAL EXPERT REVIEW BY THE ROYAL COLLEGE OF PHYSICIANS

The Royal College of Physicians (RCP) has been commissioned to undertake a review of the service, comprising three separate elements:

i. A retrospective casenote review of 32 patients who died while on the waiting list for TAVI between 2015 and 2018

The RCP's final report of the casenote review has been received and a detailed action and communication plan has been developed in response to the report's recommendations. The assurance framework contains additional assurance measures, reporting to the Quality and Safety Committee.

ii. A site review by an expert panel convened by the RCP to provide assurance regarding the improvements made to date, and to advise on any further service changes required.

The RCP review team visited the UHB for two days on 22-23 July 2019. The final report has been received and an action plan developed in response to the 21 recommendations made. The actions and progress have been reported to the Quality and Safety Committee for assurance.

iii. Further casenote review by the RCP

Based on the conclusions of the initial casenote review, the Executive Medical Director has asked the RCP to undertake a further review of 52 casenotes of patients who died on the TAVI waiting list. The RCP have completed the casenote review and the report is awaited.

4. ASSURANCE MEASURES

The assurance frameworks for delivery of the RCP's recommendations for both the casenote review (Appendix 1) and site visit (Appendix 2) detail the recommendations made by the RCP and the actions undertaken by the Health Board.

These actions have resulted in substantial improvements to the service. The quality and safety of the service is now monitored through an agreed set of metrics as a Quality and Safety Dashboard (Appendix 3) which provides significant assurance regarding current outcomes.

The level of improvement that has been achieved is highlighted by the contrast with the position in November 2018, when there were 63 patients who had been waiting over 26 weeks for a TAVI and there had been 21 deaths on the waiting list during 2018 alone. No patients have died while waiting for a TAVI since May 2019.

Significant assurance can also be taken from the way in which the Cardiology team have embraced the need to change and have made improvements at pace. They continue to refine the way in which the service is delivered and are advancing plans for the management of TAVI within an over-arching aortic stenosis pathway.

Feedback has been pro-actively sought from service users. The quality of communication between the TAVI service and partners, especially other clinicians, had been a significant concern of the RCP review team. However, the changes made to the service have been received favourably by clinicians in partner organisations, who have noted the positive improvements in communication.

The improvement work continues to have close executive oversight through a fortnightly meeting chaired by the Executive Medical Director, and through reporting to the Quality and Safety Committee.

5. GOVERNANCE AND RISK ISSUES

There remain challenges to maintaining the waiting list position given the component waiting times and the potential for patients to be referred in to the service at a late stage in their pathway. The service has been impacted by the COVID pandemic due to the need to pause the service in March. Emerging from the first wave of COVID, the demand for TAVI has risen due to the transfer of patients from the surgical aortic valve replacement list.

While the COVID-19 pandemic affected the service during the first wave, the department implemented additional operating lists from July which meant that the modest backlog was cleared.

6. COMMUNICATION

We have kept in communication with patients' families. The COVID pandemic has meant we have not been able to arrange face-to-face meetings as we had planned. We have been in contact with relatives to offer the opportunity of having either 'virtual' (Zoom/Teams) meetings, or have given them the option of waiting until the situation permits direct discussion.

7. FINANCIAL IMPLICATIONS

The costs associated with addressing the immediate backlog were originally identified as a financial pressure in region of up to £2 million. The forecast is that the commitment has reduced to £1.1m with lower numbers of patients than first anticipated and revision in mechanism of service provision.

8. RECOMMENDATION

Members are asked to:

- **AGREE** the effectiveness of the changes implemented and that these are evidenced against best practice standards.
- **AGREE** to continued oversight of the service in order to ensure the changes made are embedded and sustainable
- **AGREE** that the response to the further casenote review will be overseen by the Quality and Safety Committee
- **NOTE** that the costs of the improvements to the service are accounted for within the financial forecast.

Governance and Assurance		
Link to Enabling Objectives ***(please choose)***	**Supporting better health and wellbeing by actively promoting and empowering people to live well in resilient communities**	
	Partnerships for Improving Health and Wellbeing	☐
	Co-Production and Health Literacy	☐
	Digitally Enabled Health and Wellbeing	☐
	Deliver better care through excellent health and care services achieving the outcomes that matter most to people	
	Best Value Outcomes and High Quality Care	☒
	Partnerships for Care	☒
	Excellent Staff	☒
	Digitally Enabled Care	☐
	Outstanding Research, Innovation, Education and Learning	☒
Health and Care Standards		
(please choose)	Staying Healthy	☐
	Safe Care	☒
	Effective Care	☒
	Dignified Care	☐
	Timely Care	☒
	Individual Care	☒
	Staff and Resources	☒
Quality, Safety and Patient Experience		
This paper describes how the Health Board is ensuring that there is expert external review of the TAVI service so that lessons can be learned to drive improvement in quality, safety and patient experience.		
Financial Implications		
Forecast commitment of £1.1m		
Legal Implications (including equality and diversity assessment)		
The Health Board will need to consider redress for any breach of duty of care.		
Staffing Implications		
Having clear and dedicated clinical leadership for the TAVI service may require releasing clinical sessions from other direct clinical care duties. Consideration to be given how the ongoing improvement work will be supported and whether additional resource may be required.		
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)		
Report History		
Appendices	Appendix 1: TAVI Casenote Review Assurance Framework Appendix 2: TAVI Site Visit Assurance Framework Appendix 3: TAVI Quality and Safety Dashboard	

Updated January 2021

Assurance Framework for the delivery of the Royal College of Physicians' recommendations relating to the TAVI casenote review

Recommendation 1. The Health Board should undertake further clinical record review considering the findings relating to the clinical management of 26 sets of case notes under terms of reference 3. The Health Board has already been in discussion with the RCP ISR team about conducting this further clinical record review.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Determine the number of additional casenotes to be reviewed in a second cohort by the RCP	The casenotes of the remaining patients who died while waiting for a TAVI between 2015 and 2018 will be forwarded to the RCP for review	**Completed**			
	Patients who died while waiting for a TAVI between 2009 (the commencement of the service) and 2015 have been identified and will be forwarded to the RCP for review	**Completed**			
	One concern raised by a family member regarding a relative who died while waiting for a TAVI will also be forwarded to the RCP for review	**Completed**			
Commission the RCP to undertake a review of a second cohort of patients' casenotes	A formal request has been made from the Executive Medical Director to the RCP's Invited Service Review team	**Completed**			

Recommendation 2. The Health Board must review the pathway for patients who may be suitable for TAVI. The pathway should reflect the natural history of severe aortic stenosis and offer timely assessment of patients, coupled with timely provision of TAVI for those patients who are suitable.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Servicel Director, Morriston Hospital

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Review of the TAVI pathway to ensure that patients are on a defined pathway and that assessment and treatment occur in a timely way	There is now a clear process to ensure that there is an agreed definition of when patients on the aortic stenosis pathway are placed on the waiting list for TAVI procedure	**Completed**	Monthly report of component waiting times for TAVI	Quality and Safety Committee	Monthly for minimum 12 months
	Clear the waiting list of patients who are overdue for TAVI procedure	**Completed**	None	None	None
	Undertake a demand/capacity analysis to ensure deliverability of current service within commissioned timescales	**Completed**	Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales	WHSSC commissioning meeting with Health Board; reported to Quality and Safety Committee	July 2020
Review standards set by the British Cardiac Intervention Society (BCIS)	A multidisciplinary workshop has been held to secure consensus regarding the standards required	**Completed**	Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales	WHSSC commissioning meeting with Health Board; reported to Quality and Safety Committee	July 2020
Ensure service is able to deliver appropriate standard of care within a timeframe that reflects the natural history of aortic stenosis	Demand/capacity analysis for 18 week pathway	**Completed**	None	None	None
	Review the commissioning arrangements with WHSSC to align with BCIS standards and component waiting times	**Completed**	Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales	WHSSC commissioning meeting with Health Board; reported to Quality and Safety Committee	July 2020

Recommendation 3. The Health Board should review the way referrals to the TAVI service are received and responded to. Given the apparent constraints on the service, it may consider that all referrals should be pooled and then prioritised according to clinical need.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Review process for receiving and processing referrals	A single common electronic referral route for TAVI has been established	**Completed**			
Ensure that pathway design enables compliance with WHSSC commissioning criteria	Pathway conforms to WHSSC commissioning criteria	**Completed**			
Implement system of pooled referrals	Pooled referral system implemented	**Completed**	Quarterly audit of referrals processing	Quality and Safety Committee	Quarterly for minimum 12 months

<u>Recommendation 4.</u> The Health Board should agree with local hospitals a mechanism for inpatient transfer of patients into the TAVI service at Morriston Hospital.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Clinical Director for Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
Communicate need to actively refer patients needing TAVI to the relevant consultant team to plan admission	Communication with all referring centres and process agreed	**Completed**
Circulate process and contact details to referring clinicans across the network and partner organisations (WAST, Hywel Dda University Health Board)	Communication with all referring clinicians distributed.	**Completed**
Agree cardiac centre escalation policy for bed capacity with specific reference to recommended transfer time for TAVI	Cardiac Centre escalation policy reviewed and approved at Cardiac Board	**Completed**

Additional Actions	Assurance Group	Updated timescales for completion
Monitor performance on timely transfer	Quality and Safety Committee	Monthly for minimum 12 months

<u>Recommendation 5.</u> The cardiothoracic surgeons and cardiologists, both TAVI and non-TAVI, at Morriston Hospital, should consider how best to ensure greater coherence in the review of patients who may be suitable for TAVI, with the aim of reducing referrals between surgeons and cardiologists. One option is to run a joint TAVI clinic with TAVI cardiothoracic surgeons and TAVI cardiologists.	
Recommended timescale for completion: Medium term 6-12 months	Lead Officer: Clinical Director for Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
Establish joint clinic with Cardiology and Cardiothoracic Surgery	Joint clinic established, involving Cardiologist and Cardiothoracic surgeon - commenced July 2019	**Completed**

Additional Actions	Assurance Group	Updated timescales for completion
Quarterly audit of attendance	Quality and Safety Committee	Quarterly for minimum 12 months

<u>Recommendation 6.</u> The patient pathway should make clear the expectation regarding when MDT discussion of a case should take place (including with respect to BAV) and the timing of MDT discussion should allow for the clinical prioritisation of deteriorating patients. Patients should be advised when MDT discussion of their case is to happen and be told of the outcome in a timely fashion. The outcome of the MDT should be clearly documented in the case records.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Clinical Director for Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
Implement stand-alone MDT meeting held separately to TAVI Joint Clinic	Weekly standalone MDT meeting commencing February 2020.	**Completed**
Frequency of the MDT to reflects the need to make prompt decisions; membership of MDT has appropriate multidisciplinary representation		**Completed**
Patient to be informed of date when case is to be discussed at MDT	Electronic record and scheduling of TAVI MDT set up via Cardiology PATS system with NWIS-agreed interface to upload to WCP. Automatic letter generation to patient, referring clinician and GP enabled. Go Live date for system in February 2020.	**Completed**
Patient to be assigned responsible consultant for overseeing care		**Completed**
Documentation of MDT discussion and decision		**Completed**
Communication of MDT discussion and decision **with patient**		**Completed**
Documentation of MDT discussion and decision **with referring clinician and GP**		**Completed**

Additional Actions	Assurance Group	Updated timescales for completion
Audit to give assurance of effective MDT working	Quality and Safety Committee	Quarterly for minimum 12 months

<u>Recommendation 7.</u> The clinicians providing the service should make clear to patients and referring clinicians, and in the clinical records, when a patient is on the waiting list for TAVI, the arrangements for review whilst they are waiting, and the process for clinical prioritisation should the patient deteriorate.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Clinical Director for Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Communication to patients: Confirm date/time of their MDT discussion (see R6)	Electronic record and scheduling of TAVI MDT has been via Cardiology IT system with NWIS-agreed interface to upload to Welsh Clinical Portal. Automatic letter generation to patient, referring clinician and GP enabled. Go Live date for system in February 2020.	**Completed**	Audit of communications with patients/GPs/referrers to ensure system is robust	Quality and Safety Committee	Quarterly for minimum 12 months
Communication to patients: Confirm outcome of MDT discussion (see R6)		**Completed**			
Communication to patients: Confirm process for review		**Completed**			
Communication to patients: Confirm process for escalation		**Completed**			
Communication to referring clinician: Confirm date/time of their MDT discussion (see R6)		**Completed**			
Communication to referring clinician: Confirm outcome of MDT discussion (see R6)		**Completed**			
Communication to referring clinician: Confirm process for review		**Completed**			
Communication to referring clinician: Confirm process for escalation		**Completed**			
Documentation in clinical record to reflect communication to patient and referring clinician - as described above		**Completed**			

Recommendation 8. The role of TAVI coordinator should be given greater prominence and be made an integral element of the patient pathway. The coordinator should be responsible for making sure that momentum is maintained for every patient being considered for TAVI and should be supported by a clear plan for escalation if the pathway is not operating efficiently.	
Recommended timescale for completion: Medium term 6-12 months	Lead Officer: Service Director, Morriston Hospital

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Appointment of TAVI Clinical Nurse Specialist (CNS)	TAVI CNS appointed	**Completed**			
Priority within job plan to manage all patients on TAVI pathway	Agreed within role of TAVI CNS	**Completed**			
Priority within job plan to manage all patients on TAVI pathway	Agreed within role of TAVI CNS	**Completed**			

Recommendation 9. There should be strong clinical leadership of the TAVI service, with a named clinician responsible for overseeing the effectiveness of the patient pathway and leading the development of the service.	
Recommended timescale for completion: Medium term 6-12 months	Lead Officer: Unit Medical Director, Morriston Hospital

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Appointment of Acting Clinical Director for Cardiology	Acting CD for Cardiology appointed	**Completed**			
Acting TAVI Clinical Lead appointed	Acting TAVI Clinical Lead appointed	**Completed**			
Formal appointment of Clinical Director for Cardiology	CD for Cardiology appointed	June 2020 **Completed**			
Formal appointment of Clinical Lead for TAVI		**Completed**			

Recommendation 10. There must be unequivocal clinical ownership of each patient's care, a named clinician who oversees a patient's journey and ensures that there is a coherent management plan for the patient, the treatment decisions are made in a timely way; and that decisions reflect MDT discussion.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Clinical Director, Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Named clinician responsible for every patient	Named clinician for every patient allocated by MDT. Clarity regarding responsibility of each named clincian to ensure that there is a coherent management plan for the patient, the treatment decisions are made in a timely way; and that decisions reflect MDT discussion (see also R6)	**Completed**	Audit of process to allocate named consultant	Quality and Safety Committee	Quarterly for minimum 12 months

Recommendation 11. Investigations needed to establish whether a patient is suitable for TAVI should be ordered in parallel as far as possible, to get the process moving.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Clinical Director, Cardiology

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
Agree and document minimum set of investigations prior to TAVI	Minimum set of investigations prior to TAVI documented within referral pathway.	**Completed**
Agree in pathway that investigations are ordered in parallel	Investigations ordered in parallel as matter of course through referral pathway and MDT where required.	**Completed**

Additional Actions	Assurance Group	Updated timescales for completion

Recommendation 12. The cardiologists should stop routine ordering of TOEs for TAVI evaluation and swicth to computerised tomography (CT) scan for 95% of patients. Where TOE is considered necessary, the Health Board must take steps to reduce the waiting time for this investigation.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
Ensure CT is the investigation of choice rather than TOE	Pathway reflects CT as investigation of choice	**Completed**
	Review of current proportion of patients having CT rather than TAVI - confirms CT as the primary investigation	**Completed**

Additional Actions	Assurance Group	Updated timescales for completion
Establish clear criteria for use of TOE in cases where CT is not possible/appropriate	Quality and Safety Committee	June 2020
Establish capacity required to deliver required CT capacity to support the TAVI pathway to take component waiting times into account	Quality and Safety Committee	June 2020

Recommendation 13. The Health Board should make provision for relatives of the 32 patients covered by this review to discuss with a cardiologist the case summary relevant to their relative at Appendix 2. The Health Board should ensure that Duty of Candour is enacted for those instances where patients were deemed to have received unsatisfactory care.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Head of Patient Experience

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Initial communication with families and next of kin of the first cohort of patients to inform them that RCP will be reviewing casenotes	Communication with families and next of kin	**Completed**			
Communication to inform families and next of kin that casenote review has been completed and offer time to meet to discuss	Communication with families and next of kin	**Completed**			
Offer meetings with families to discuss outcomes of the review and the RCP's findings with regard to their relative	Communication with families and next of kin	**Completed**			

Recommendation 14. The Health Board should consider this report at a relevant Board quality assurance committee and develop an action plan to address the recommendations made.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
Regular updates have been provided to the Health Board and Quality and Safety Committee (In-Committee) over the past 12 months, including updates on correspondence with the RCP, outline draft reports and planned additional input from RCP (site visit in July 2019 and planned casenote review of a second cohort of patients)	Agendas of Health Board and Quality and Safety Committee	**Completed**	Monthly report to be provided for oversight and scrutiny of delivery of action plan and ongoing compliance with actions	Quality and Safety Committee	Monthly for minimum 12 months
Action plan developed in response to the report's recommendations	Document: Assurance Framework for the delivery of the Royal College of Physicians' recommendations relating to the TAVI casenote review	**Completed**			
A report will be presented and discussed at a formal meeting of the Health Board		**Completed**			

Recommendation 15. The Health Board should consider sharing the outcome of this report with the relevant bodies in Wales, to include Health Inspectorate Wales, the Welsh Health Specialist Service Commissioning and Chief Medical Officer for Wales.	
Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale
The report has been shared with Welsh Government, including the Chief Medical Officer (CMO) for Wales	Correspondence with Welsh Government; meeting with Welsh Government officials and the CMO's office	**Completed**
The report has been shared with Welsh Health Specialised Services Committee (WHSSC) as commissioners	Meeting with representatives of WHSSC	**Completed**
The report has been shared with Hywel Dda University Health Board	Meeting with representatives of Hywel Dda UHB	**Completed**
The report has been formally shared with Health Inspectorate Wales (HIW)	Report shared with HIW	**Completed**
All Health Boards whose patients were involved in this review have been informed of the review's findings and the actions being taken	Other HBs informed	**Completed**

Additional Actions	Assurance Group	Updated timescales for completion

Swansea Bay University Health Board January 2021

Assurance Framework for the delivery of the Royal College of Physicians' recommendations relating to the TAVI Site Visit review

Recommendation 1. The Health Board should also consider sharing the outcome of this report with the relevant bodies in Wales, to include Health Inspectorate Wales, the Welsh Health Specialist Service Commissioning and chief medical officer for Wales.

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Executive Medical Director

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Outcome of report to be shared with HIW, WHSSC and Welsh Government.	Outcomes shared with key stakeholders	Completed	None		

Recommendation 2. The Health Board should appoint a single designated clinical lead for the TAVI service, with time recognised in the job plan for leadership, case planning, MDT and developing the service.

Recommended timescale for completion: Immediate (0-3 months) | Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Appointment of Clinical Lead	Appointment made to Clinical Lead post	Completed	None		
b	Job plan to include dedicated time for leadership, case planning, MDT and service development	Job plan to reflect time required to deliver in the role.	Completed	None		

Recommendation 3. The Health Board should review its TAVI pathway against the new service specification for TAVI published by the British Cardiovascular Intervention Society, including the concept of a 'Heart Team', the recommended MDT structure, and other pathway recommendations. This work would be informed by observing TAVI services at other centres to understand procedural flow.

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Evaluate current service specification against BCIS recommendations	Formal assessment of service against BCIS	Completed	None		
b	Link with another UK centre	Formal link with another UK centre and share good practice	Completed	None		

Recommendation 4. **The membership of the TAVI MDT and TAVI planning meeting (the second MDT) should align with guidelines, as outlined in the conclusions for terms of reference 1.**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Membership of TAVI MDT aligns with guidelines	Formal review of MDT membership against guidelines	Completed	None		
b	Membership of TAVI planning meeting aligns with guidelines	Formal review of TAVI planning meeting membership aginst guidelines	Completed	None		

Recommendation 5. **MDT decisions should be clearly documented and shared with relevant staff, as well as patients, GPs and referring centres. Decisions on valve type, access route and procedural complexities should be made at the MDT planning meeting and communicated to the cath lab team well in advance of the TAVI list. Shared decision making with patients is key and details of options discussed and agreed with patients should feature in the MDT records.**

Recommended timescale for completion: Short term (0-6 months) | Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	MDT decisions documented	Decisions and outcomes recorded electronically at the meeting via Solus system.	Completed	Audit of MDT documentation	Quality & Safety Committee	Quarterly for 12 months
b	MDT decisions shared with staff, GPs and referrers	Electronic outcome notes are uploaded to WCP and communicated with GPs and patients.	Completed	Audit of MDT documentation	Quality & Safety Committee	Quarterly for 12 months
c	MDT record reflects options discussed and agreed with patient	Summary of decision making and discussion is transcribed into standard agreed format at the MDT meeting which is uploaded to WCP.	Completed	Audit of MDT documentation	Quality & Safety Committee	Quarterly for 12 months
d	Type of valve to be used, access route & procedural detail to be communicated with catheter lab staff	Written detail of planned procedures including patients booked, access route and valve type is circulated a week in advance to all cath lab, ward and operational staff. Detail further reiterated in TAVI briefing checklist on day of procedure.	Completed	Audit of MDT documentation	Quality & Safety Committee	Quarterly for 12 months

Recommendation 6. **Given the problems experienced previously, the Health Board should routinely audit the impact of new MDT decision-making arrangements, by checking with GPs, patients and referring cardiologists that documentation regarding decisions explains the MDT's recommendations, including next steps and whether the patient is on the waiting list for TAVI, with sufficient clarity.**	
Recommended timescale for completion: Long term (12-24 months)	Lead Officer: Directorate Manager, Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Audit MDT communication and documentation to ensure essential information conveyed	Formal audit of MDT communication	Completed	Ongoing audit of MDT communication	Quality & Safety Committee	Quarterly for 12 months
b	Seek feedback from GPs and referrers regarding the quality of information shared and that they are satisfied that this clearly describes the MDT recommendation, next steps and whether the patient is on the TAVI waiting list	Formal stakeholder opinions canvassed	Completed	Ongoing stakeholder review	Quality & Safety Committee	Bi-annually 12 months
c	Clear details provided for patients and referrers to contact the service	Patient information leaflet contains contact details for TAVI CNS team. TAVI MDT information also provided to patients and referrers.	Completed			

Recommendation 7. **The Health Board should encourage the cardiologists who provide the TAVI service to learn TAVI CT reporting. This will involve providing protected time for learning and ensuring adequate cover is in place. An imaging cardiologist is needed in the MDT TAVI planning meeting; someone expert in echocardiograms and possibly cardiac CT.**

Recommended timescale for completion: Short term 0-6 months	Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Establish ability of Cardiologists to report TAVI CT; facilitate training for Cardiologists who wish to develop this skill	Valve choice, sizing and procedural planning performed after CT analysis by the TAVI cardiologists using bespoke CT analysis software (3mensio, 3mensio Medical Imaging BV). This is led by two cardiologists who are fully trained in cardiac CT (Drs Obaid and Khurana). They have trained Dr Smith and Professor Chase in CT analysis for TAVI cases and are in the process of training Dr Hailan, such that every TAVI operator will be responsible for analysing CT scans for TAVI. In the week before the TAVI procedure this analysis is double-checked by the two cardiologists who will be performing the procedure.	Completed	None		
b	Imaging specialist available for TAVI MDT covering range of modalities (echo, CT)	MDT has representation from imaging specialists covering Cardiac CT and MR and echocardiography.	Completed	None		

Recommendation 8. **The Health Board should expedite plans for an additional nursing appointment and for dedicated administrative support. It should consider whether 0.4 whole time equivalent (WTE) administrative support will be enough and whether the second nursing position could be reduced to 0.6 WTE, instead of 0.8 WTE currently planned, in order to increase the administrative support within the same financial envelope.**

Recommended timescale for completion: Short term (0-6 months)	Lead Officer: Directorate Manager, Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Appointments made to nursing posts	Appointments made	Completed	None		
b	Appointments made to admin posts	Appointment in progress, interviews scheduled for 03/09/2020	Completed			

Recommendation 9. **The Health Board should establish which cardiologists will support the service going forward and the level of commitment they will give, which should be clearly articulated in job plans. Job plans should also reflect recommendation 10, below.**

Recommended timescale for completion: Short term (0-6 months)	Lead Officer: Clinical Director of Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Confirmation of which consultants support TAVI	A total of five consultants will perform TAVI procedures, as well as review patients in clinic, present in the MDT, perform CT analysis and provide post procedure care. A 16 week rolling rota has also been developed to allow 2 all day TAVI lists per week. Each list will be led by a senior operator (Dr Smith and Prof Chase) to facilitate training of less experience operators. The other consultants are Dr Khurana, Dr Obaid and Dr Hailan. These arrangements to be formalised via job planning process in the coming months.	Completed	None		
b	Commitment to TAVI articulated in job plans	Confirmation from Clinical Director for Cardiology following agreement with consultants	January 2021	None		
c	Job plans for TAVI consultants to reflect expetations for leadership and engagement	Confirmation from Clinical Director for Cardiology following agreement with consultants	January 2021	None		

Recommendation 10. **The Standard Operating Procedure (SOP) for the TAVI service should articulate the Health Board's expectations for:**
a. Clinical ownership of patients receiving TAVI before, during and after the procedure
b. The cardiologists to demonstrate leadership for the wider team
c. The cardiologists to engage proactively with consultant colleagues in other specialties to plan contingency arrangements for patients where problems may be encountered, and to involve colleagues in these arrangements early on
d. Attendance at cath lab team briefings on the TAVI list.

Recommended timescale for completion: Short term 0-6 months	Lead Officer: Executive Medical Director

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Expectations of Health Board regarding TAVI service articulated in letter from Executive Medical Director to all consultants in Cardiology and Cardiac Surgery		Completed	None		

Recommendation 11. **The TAVI team should develop a more integrated approach to dealing with the issues of consent and TAVI emergencies. Shared decision making/discussion with patients around potential 'bail out' options should take place in clinic and prior to a patient's procedure.**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Clinical Director, Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Decisions regarding escalation in care and 'bail-out' to be made in MDT	Formal incorporation of agreed escalation and ceilings of care in MDT documentation	Completed	None		
b	Shared decision-making with patients around escalation and 'bail out'	MDT documentation records shared decision-making with patient	Completed	None		

Recommendation 12. **The Health Board should review the designation of beds for TAVI, on the ward and for recovery and intensive care. Priority in terms of beds should be given to patients requiring TAVI ahead of non-life-threatening conditions. Patients requiring intensive care should be cared for on the cardiac intensive care unit (ITU), not the general ITU.**

Recommended timescale for completion: Medium term (6-12 months) | Lead Officer:

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Standard Operating Procedure for TAVI to include clear designation of beds post-procedure	Formalisation in SOP	Completed	None		
b	Standard Operating Procedure to specify Cardiac ITU rather than General ITU for TAVI patients who require Level 3 care	Formalisation in SOP	Completed	None		

Recommendation 13. **The Health Board should make a substantive appointment to the position of clinical director for cardiology as soon as possible.**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Unit Medical Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Appointment of Clinical Director for Cardiology	Substantive appointment made	Completed	None		

Recommendation 14. **The Health Board should forge links with the TAVI service in appropriate UK centres to agree a set of referral guidelines for patients in Wales.**

Recommended timescale for completion:Long term (12-24 months) | Lead Officer: Clinical Director for Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Establish formal link with another UK TAVI centre	Formalisation of link with another UK centre - agreement between senior leaders. See R3(b), above.	Completed	None		
b	Referral guidelines agreed	SB contributing to national referral guidelines being coordinated by WHSSC	Completed	Seek feedback from referrers		

Recommendation 15. **The Health Board should continue to be vigilant to the risk of a deterioration in TAVI waiting times for the TAVI service, and the impact on life expectancy for those patients awaiting. The risk score should reflect ongoing concerns regarding the sustainability of the current service. The TAVI service needs to remain high on the corporate risk register.**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Service Director, Morriston Hospital

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	TAVI waiting list to be reviewed at weekly operational meeting	Minutes of fortnightly Silver operational meeting	Completed	None		
b	TAVI remains of Health Board Risk Register	TAVI on Health Board Risk Register	Completed	Risk Register reviewed monthly and evaluated against progress with action plan	Quality and Safety Committee	Quarterly for 18-24 months

Recommendation 16. **The Health Board must ensure that all incidents related to TAVI are captured in a single database, and that staff understand the importance of reporting incidents on Datix, to provide a complete and coherent picture of incidents.**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Clinical Director for Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	All TAVI incidents to be captured in DATIX	Recording of TAVI incidents in DATIX	Completed	Incidents reviewed at TAVI M&M meeting monthly; all incidents escalated to Delivery Unit Senior Team and TAVI Gold command; reviewed by Corporate Patient Safety team	Quality and Safety Committee	12 months

Recommendation 17. **The Health Board should establish a specific TAVI morbidity & mortality (M&M) meeting, attended by the TAVI cardiologists, TAVI clinical nurse specialist (CNS) and other staff who support the service. The meeting should be minuted and the minutes shared widely, so that learning can be spread. There should be some element of externality to these meetings. Once established, it should be a priority for the TAVI M&M to review mortality over the previous six months**

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Clinical Director for Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Multidisciplinary TAVI Morbidity and Mortality meeting established	TAVI M&M meeting established	Completed	Minutes of TAVI M&M meeting reviewed monthly in Delivery Unit Quality and Safety meeting; issues to be escalated to TAVI Gold. Bi-annual review of TAVI M&M meeting notes	TAVI Gold command meeting	12 months
b	TAVI M&M meeting to include 6-monthly review of mortality	TAVI M&M agenda to include 6-month mortality review	Completed	Minutes of TAVI M&M meeting reviewed monthly in Delivery Unit Quality and Safety meeting; issues to be escalated to TAVI Gold. Bi-annual review of TAVI M&M meeting notes	TAVI Gold command meeting	12 months

Recommendation 18. **The TAVI cardiologists should agree on a named audit lead for TAVI. All the consultant cardiologists should take responsibility for inputting outcome data into the BCIS database. TAVI data for the previous year should be presented and discussed within the TAVI team, as well as with cardiac surgeons and other clinicians who support the service.**

Recommended timescale for completion: Medium term (6-12 months) | Lead Officer: Clinical Director for Cardiology

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Appointment of named audit lead for TAVI	Named Audit Lead identified for TAVI	Completed	None		
b	Audit lead to present TAVI data to multidisciplinary team	Audit data presented to MDT	Completed	None		

Recommendation 19. **The Health Board should resist any expansion or innovation of the TAVI service in terms of access, techniques and devices, until it can be confident that existing provision is meeting the requirements of a modern TAVI service and that any issues around complications have been identified and corrected**

Recommended timescale for completion: Long term (12-24 months) | Lead Officer: Exectutive Medical Director

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Any proposal for new form of access, technique or device to be accompanied by Standard Operating Procedure and assurance regarding ability to deliver safely	Submissions to TAVI Gold Command	Completed	Initiation of any new form of access, technique or device to be reported as part of the quality report to Quality and Safety Committee	Quality and Safety Committee	24 months
b	Service developments to align with national best practice and ensuring the TAVI service is up to date	Submissions to TAVI Gold Command	Completed			

Recommendation 20. **The cardiologists and cardiac surgeons should support the move led by the commissioners to develop an aortic stenosis pathway. All parties should consider the evidence base in support of TAVI for younger and lower risk patients.**

Recommended timescale for completion: Long term (12-24 months) | Lead Officer: Executive Medical Director

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Secure support of all clinicians for the development of an aortic stenosis pathway	Agreement with clinicians - discussed with Executive Medical Director	Completed	None		

Recommendation 21. **The Health Board should undertake further work to establish the cause of the vascular complications that have occurred this year and to identify actions to prevent their occurrence. This should include:**
a. Early identification of any cases where vascular access is likely to be difficult and proactive discussion of these cases at the vascular MDT
b. Developing a TAVI femoral puncture recovery protocol for the lab and wards
c. For the TAVI cardiologists to improve their closure techniques either by going to another centre to learn (the RCP can offer suggestions) or inviting someone in to teach.

Recommended timescale for completion: Short term 0-6 months | Lead Officer: Executive Medical Director

	Key actions taken to meet the requirements of the recommendation	Evidence to support action completion	Completion timescale	Additional Actions	Assurance Group	Updated timescales for completion
a	Audit of all vascular complications	Comprehensive audit of vascular complications	Completed			
b	Development of Standard Operating Procedure for all types vascular access	Standard Operating Procedures developed for all types of vascular access (femoral and sub-clavian)	Completed			
c	Ensure training of ward staff in managing post-TAVI care	Evidence of training programme for all staff and evidence of participation	Completed			
d	Establish link with other UK centre to share good practice	See R3(b), R14(a)	Completed			

TAVI Service Quality & Safety Dashboard

Measure	Benchmark [1]	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Financial Year to date
Number of procedures completed		**2**	**4**	**24**	**21**	**12**	**17**	**7**	**13**	**11**				111
Procedural deaths (%)	2%	0	0	0	0	25% (1)	0	0	0	0				1% (1)
In-hospital deaths (%)	2%	0	0	4.2% (1)	0	0	0	0	0	0				1% (1)
30 day mortality (%)	5%	0	0	0	0	0	0	0	0	0				0%
VARC-2 Major Complications (%)	2.3%	0	0	0	0	0	0	0	0	0				0%
Stroke (%)	2.6%	0	0	0	0	0	0	0	0	0				0%
Pacemaker post TAVI (%)	12%	0	0	12.5% (3)	9.5% (2)	25% (3)	0	14% (1)	0	9.1% (1)				9% (1)
Migration/ectopic deployment (%)	1.1%	0	0	0	0	0	0	0	1	0				1%
Length of stay (days TAVI to discharge)	5.5	2	2	1.8	2	2	2	2.3	2.2	4.1				2.26
RTT (number of patients >36 weeks at end of month)	0	0	3	5	2	0	0	0	2	3				1.6 (mean)
Allocation of Named Consultant for TAVI patients (% compliance)	100%	100	100	100	100	100	100	100	100	100				100%

1. All benchmarks based on British Cardiovascular Intervention Society (BCIS) data, with the exception of ***30-day-mortality*** *which is based on International RCT data and* ***RTT*** *which is based on WG target.*