Trans-Catheter Aortic Valve Insertion (TAVI) Progress Report Presenter: Dr Philip Kloer

TAVI Progress Report October 2020

Appendix 1 2020-07-31 TAVI Update_v02

Appendix 2 - TAVI Cohort 1 Action Plan_July 2020

Appendix 3 - TAVI Quality Dashboard July 2020



PWYLLGOR ANSAWDD, DIOGELWCH A SICRHAU PROFIOD QUALITY, SAFETY AND EXPERIENCE ASSURANCE COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	06 October 2020
TEITL YR ADRODDIAD: TITLE OF REPORT:	Trans-Catheter Aortic Valve Insertion (TAVI) Progress Report
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Dr Philip Kloer, Medical Director and Deputy CEO
SWYDDOG ADRODD: REPORTING OFFICER:	John Evans, Assistant Director, Medical Directorate

Pwrpas yr Adroddiad (dewiswch fel yn addas) Purpose of the Report (select as appropriate) Er Sicrwydd/For Assurance

ADRODDIAD SCAA SBAR REPORT Sefyllfa / Situation

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 the external review of the service by the Royal College of Physicians (RCP). This service is provided by Swansea Bay University Health Board (SBUHB) and the update has been provided in co-operation with the Medical Director, SBUHB

Cefndir / 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, S BUHB convened an executive-led 'Gold Command' Group to oversee improvement actions.

Asesiad / Assessment

RCP case note review

The Royal College of Physicians reviewed the case notes of 32 patients who had died while waiting for a TAVI between 2015 and 2018:

- Overall, they found that there were concerns in 23 of the 32 cases;
- 17 cases of the 32 cases related to Hywel Dda UHB patients;
- Of the 17 patients from Hywel Dda, concerns were raised in 13 cases. As per the action plan submitted by SBUHB, families and carers of patients involved were contacted to inform them of the review, to gather feedback, to share details of the report (and details

of their individual cases), to offer meetings, support and any further information they might need. A helpline is available for families who SBUHB have contacted directly.

SBUHB have commissioned the RCP to undertake a review of a second cohort of patients. This will conclude a review of all patients who have passed away whilst waiting for a TAVI from the time the service began in 2009, through to 2019. For this second cohort of 51 patients, 22 were from Hywel Dda UHB. It is expected that the final report will be available in 3-6 months and this will be duly published and shared at that time. The relatives or next of kin of all patients in this second cohort have already been contacted to inform them that a review will take place, and have been given contact details for the patient experience team in SBUHB should they wish to discuss the matter further.

The service at Morriston Hospital was paused from 25th March 2020 due to COVID-19 but recommenced from July 2020, as part of the Quarter 2 operational plan. The waiting list position in September 2020 is as follows:

- Patients >52 weeks = 0
- Patients >36 weeks = 0
- Patients >26 weeks = 2
- Patients >18 weeks = 25
- Patients <18 weeks = 22

The HDdUHB Medical Director, has been liaising with his counterpart in SBUHB regularly in relation to the inpatient waits for TAVI services. In addition, the Medical Director in SBUHB oversees and monitors the waiting list on a weekly basis.

Whilst the Health Board awaits the final RCP report and recommendations from SBUHB, the following supporting documents are attached in order to provide assurance to QSEAC regarding the progress made in treating those patients on the TAVI waiting list.

- The current TAVI update from SBUHB (Appendix 1)
- The current action plan (Appendix 2)
- TAVI Quality Dashboard (Appendix 3)

Argymhelliad / Recommendation

For the Committee to receive assurance from the progress made in treating those patients on the TAVI waiting list.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)	
Committee ToR Reference:	5.9 Provide assurance to the Board in relation to
Cyfeirnod Cylch Gorchwyl y Pwyllgor:	its responsibilities for the quality and safety of
	public health, health promotion, prevention and
	health protection activities and interventions in line
	with the Health Board's strategies.
Cyfeirnod Cofrestr Risg Datix a Sgôr	105, 107, 117, 118, 119, 120, - risks relating to
Cyfredol:	Cardiology services
Datix Risk Register Reference and	
Score:	

Safon(au) Gofal ac lechyd: Health and Care Standard(s): 2.1 Managing Risk and Promoting Health and Safety3.1 Safe and Clinically Effective Care

Effaith/Impact:	
Ariannol / Financial: Ansawdd / Patient Care: Gweithlu / Workforce: Risg / Risk: Cyfreithiol / Legal: Enw Da / Reputational: Gyfrinachedd / Privacy: Cydraddoldeb / Equality:	Contained within the narrative of the report.

SWANSEA BAY UNIVERSITY HEALTH BOARD

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 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, which are detailed in Section 4, below.

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 Executive Medical Director has received the final report and an action plan is in development.

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. This second review includes all patients who died while on the TAVI waiting list prior to 2015 (until the initiation of the service in 2009), as well as additional cases from the 2015-2018 cohort which were not included in the first review, as well as 1 patient from 2019 and 1 complaint received directly by the Chief Executive.

Copies of the casenotes have been forwarded to the RCP's Invited Service Review team. We understand that the review has been completed and are awaiting the draft report.

4. ASSURANCE MEASURES

The assurance framework for delivery of the RCP's recommendations is attached (Appendix 1). The fifteen recommendations made by the RCP were divided into 50 separate actions, of which 49 have been completed. The outstanding action is:

• Within **Recommendation 2**: *Review the commissioning arrangements with WHSSC to align with BCIS standards and component waiting times.* The COVID pandemic necessitated rescheduling of this meeting, which will be arranged within the next 4 weeks.

A suite of assurance measures and quality metrics has been agreed, aligned to the assurance framework developed to deliver the RCP's recommendations. The Quality Dashboard is attached in Appendix 2.

Specific actions to demonstrate improved governance of the service have been agreed:

- Attendance and Effectiveness of Aortic Stenosis Joint Clinic
- Attendance and Effectiveness of Structural Heart MDT
- Audit of Communication with Patients and Referrers
- Timely transfer from other sites

Attendance and Effectiveness of Aortic Stenosis Joint Clinic

The joint Aortic Stenosis (AS) Outpatient Clinic commenced in July 2019 and enabled all patients with moderate to severe aortic stenosis, deemed high risk for surgery, to be seen by both a Cardiologist and a Cardiac Surgeon contemporaneously, for consideration of TAVI versus surgical Aortic Valve Replacement (sAVR) An audit of three months of clinic activity between September and November 2019 demonstrated the following:

	Number	%
Total patients seen in Joint AS Clinic	52	-
Sept-Nov 2019		
Proportion of patients seen in Joint	38	74%
AS clinic who proceeded to TAVI		
Proportion of patients seen in joint AS	7	14%
clinic who proceeded to sAVR		
Proportion of patients seen in joint AS	4	8%
clinic who remained under clinical		
surveillance of AS symptoms		
Proportion of patients seen in joint AS	2	4%
clinic who received no intervention for		
AS		

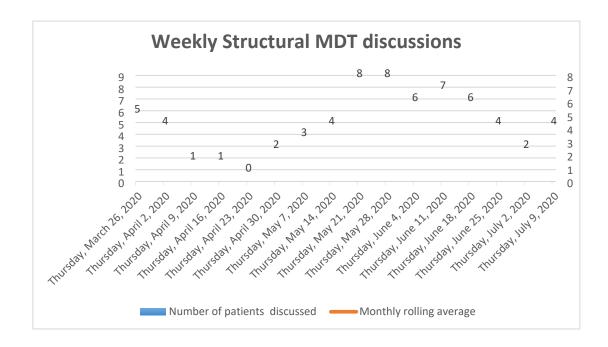
Since late March 2020, the joint clinic has been suspended due to the COVID-19 pandemic. The Structural Heart Multidisciplinary Team (MDT) has continued on a weekly basis with both Cardiology and Cardiac Surgery representation (including Clinical Nurse Specialist). All patients referred for surgical or Cardiology review of symptomatic AS have been discussed at this forum and brought into clinic on an ad-hoc basis as required.

Attendance and Effectiveness of Structural Heart MDT

Since 26th March a total of 65 patients have been discussed at the Structural Heart Disease MDT. Every meeting has had both Cardiology (general and interventional) and Cardiac Surgery representation, as well as input from the Structural Heart Disease CNS Team. The options for treatment include TAVI, surgical aortic valve replacement (sAVR), balloon aortic valvotomy (BAV) or medical management. The outcomes for all patients discussed is as follows:

MDT outcomes	Number (Total 65)	Percentage
TAVI	31	48%
SAVR and/or aortic root surgery	14	22%
Patient choice	2	3%
Palliative BAV	2	3%
Further discussion pending		
investigations	9	14%
Medical management	7	11%

Regardless of whether they are referred to Cardiology or Cardiac Surgery for intervention, all patients with aortic stenosis are now discussed at the Structural Heart MDT. The MDT meeting has continued weekly throughout the course of the COVID pandemic and numbers of patients discussed are demonstrated in the graph below.



The increased risks associated with Cardiac Surgery at the current time, as well as the constraints COVID-19 has placed on surgical capacity at Morriston, mean that an increasing number of patients of intermediate surgical risk have been recommended for TAVI instead of sAVR, following discussion at Structural Heart MDT.

Audit of Communication with Patients and Referrers

Scheduling and recording of MDT discussion and decision making is captured electronically within the meeting. A letter confirming the MDT outcome is shared with both the patient and the referrer and this letter is uploaded to Welsh Clinical Portal (WCP).

Now that the MDT is well established, the Cardiology service plans to liaise with colleagues in primary care and secondary Cardiology to capture some survey information on how referrers are finding the improvements to the service so far.

Timely transfer from other sites

Between March and June 2020, the TAVI service accepted a total of 5 out-ofarea referrals for inpatient TAVI. It is usual for patients to require a number of investigations and clinical optimisation in their parent Health Board prior to transfer for the TAVI procedure. Completion of these can impact on the timescale for transfer and work is being undertaken to streamline this process to support colleagues in other health boards and to devise a set of quality measures by which the timeliness of inpatient transfer can be monitored on an ongoing basis.

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.

Immediately prior to the COVID-19 pandemic, on 19th March 2020, there were 51 patients waiting for TAVI. Of these, 46 (90%) had been waiting less than 18 weeks; none had been waiting over 36 weeks.

The service was paused from 25th March due to COVID and recently recommenced. The waiting list position in July 2020 is as follows:

- Patients >52 weeks = 0
- Patients >36 weeks = 2
- Patients >26 weeks = 6
- Patients >18 weeks = 30

Both patients waiting over 36 weeks were transferred from the surgical aortic valve replacement waiting list due to COVID; both patients have dates for admission for TAVI. The department is currently running additional TAVI lists to catch up with the backlog of cases.

No patients have died while waiting for a TAVI since May 2019.

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.

Appendix 1

Updated July 2020

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
	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	January 2020 Completed			
Determine the number of additional casenotes to be reviewed in a second cohort by the RCP	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	January 2020 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	January 2020 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	September 2019 Completed			

Recommende	d timescale for completion: Short term 0-6 m	ionths	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	August 2018 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	March 2019 Completed	None	None	None	
	Undertake a demand/capacity analysis to ensure deliverability of current service within commissioned timescales	March 2019 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 ntervention Society (BCIS)	A multidisciplinary workshop has been held to secure consensus regarding the standards required	October 2019 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	June 2020	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	August 2018 Completed					
Ensure that pathway design enables compliance with WHSSC commissioning criteria	Pathway conforms to WHSSC commissioning criteria	August 2018 Completed					
Implement system of pooled referrals	Pooled referral system implemented	August 2018 Completed		Quarterly audit of referrals processing	Quality and Safety Committee	Quarterly for minimum 12 months	

Recommendation 4. 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	Additional Actions	Assurance Group	Updated timescales for completion
Communicate need to actively refer patients needing TAVI to the relevant consultant team to plan admission	Communication with all referring centres and process agreed	July 2019 Completed	Monitor performance on timely transfer	Quality and Safety Committee	Monthly for minimum 12 months
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.	July 2019 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	January 2020 Completed			

Recommendation 5. 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	Additional Actions	Assurance Group	Updated timescales for completion
I Establish joint clinic with Cardiology and	Joint clinic established, involving Cardiologist and Cardiothoracic surgeon - commenced July 2019	July 2019 Completed	Quarterly audit of attendance	Quality and Safety Committee	Quarterly for minimum 12 months

Recommendation 6. 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	Additional Actions	Assurance Group	Updated timescales for completion
Implement stand-alone MDT meeting held separately to TAVI Joint Clinic	Weekly standalone MDT meeting commencing February 2020.	March 2020 Completed	Audit to give assurance of effective MDT working	Quality and Safety Committee	Quarterly for minimum 12 months
Frequency of the MDT to reflects the need to make prompt decisions; membership of MDT has appropriate multidisciplinary representation		March 2020 Completed			
Patient to be informed of date when case is to be discussed at MDT		March 2020 Completed			
Patient to be assigned responsible consultant for overseeing care	Electronic record and scheduling of TAVI	March 2020 Completed			
Documentation of MDT discussion and decision	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.	March 2020 Completed			
Communication of MDT discussion and decision with patient	Go Live date for system in February 2020.	March 2020 Completed			
Documentation of MDT discussion and decision with referring clinician and GP		March 2020 Completed			

Recommendation 7. 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)		March 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		March 2020	1 [
outcome of MDT discussion (see R6)		Completed				
Communication to patients: Confirm		March 2020] [
process for review		Completed				
Communication to patients: Confirm		March 2020				
process for escalation		Completed				
Communication to referring clinician: 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	March 2020 Completed				
Communication to referring clinician: Confirm outcome of MDT discussion (see R6)	Welsh Clinical Portal. Automatic letter generation to patient, referring clinician and GP enabled. Go Live date for system in	March 2020 Completed				
Communication to referring clinician: Confirm process for review	February 2020.	March 2020 Completed				
Communication to referring clinician: Confirm process for escalation		March 2020 Completed				
Documentation in clinical record to reflect communication to patient and referring clinician - as described above		March 2020 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.

	1	Recommended	timescale for	completion:	Medium term	6-12 months	
--	---	-------------	---------------	-------------	-------------	-------------	--

Lead Officer: Service Director, Morriston Hospital

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
Appointment of TAVI Clinical Nurse Specialist (CNS)	TAVI CNS appointed	November 2018 Completed			
Priority within job plan to manage all patients on TAVI pathway	Agreed within role of TAVI CNS	August 2019 Completed			
Priority within job plan to manage all patients on TAVI pathway	Agreed within role of TAVI CNS	August 2019 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

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
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	Clinical Lead for TAVI appointed	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.

Recommende	eu umescale for completion. Short term 0-0 m	Ununs	Leau Officer.	Cillical 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)		Audit of process to allocate named consultant	Quality and Safety Committee	Quarterly for minimum 12 months

Recomme	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.								
Recommende	ed timescale for completion: Short term 0-6 mo	onths		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			
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							

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 method steps to reduce the waiting time for this investigation.						Health Board must take
Recommende	ed timescale for completion: Short term 0-6 m	onths		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
	Pathway reflects CT as investigation of choice	Completed		Establish clear criteria for use of TOE in cases where CT is not possible/appropriate	Quality and Safety Committee	June 2020
Ensure CT is the investigation of choice rather than TOE	Review of current proportion of patients having CT rather than TAVI - confirms CT as the primary investigation	Completed		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 t com
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	November 2018 Completed			
	Communication with families and next of kin	March 2020 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	March 2020 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	January 2020 Completed			
A report will be presented and discussed at a formal meeting of the Health Board		March 2020 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	January 2020 Completed
The report has been shared with Welsh Health Specialised Services Committee (WHSSC) as commissioners	Meeting with representatives of WHSSC	March 2020 Completed
The report has been shared with Hywel Dda University Health Board	Meeting with representatives of Hywel Dda UHB	March 2020 Completed
The report has been formally shared with Health Inspectorate Wales (HIW)	Report shared with HIW	March 2020 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	March 2020 Completed

nescale	Additional Actions	Assurance Group	Updated timescales for completion
20 d			
d			
20 d			
20 d			
20 d			

APPENDIX 2

TAVI Service Quality & Safety Dashboard

Measure	Benchmark ¹	Mar-20	Apr-20	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Financial Year to date (June 2020)
Number of procedures completed		13	2	4	24							30
Procedural deaths (%)	2%	0	0	0	0							0% (0)
In-hospital deaths (%)	2%	0	0	0	4.2% (1)							3.3% (1)
30 day mortality (%)	5%	0	0	0	0							0% (0)
VARC-2 Major Complications (%)	2.3%	0	0	0	0							0% (0)
Stroke (%)	2.6%	0	0	0	0							0% (0)
Pacemaker post TAVI (%)	12%	7% (1)	0	0	12.5% (3)							10% (3)
Migration/ectopic deployment (%)	1.1%	0	0	0	0							0% (0)
Length of stay (days TAVI to discharge)	5.5	3.8	2	2	1.8							1.9 (Mean)
RTT (number of patients >36 weeks at end of month)	0	0	0	3	5							3 (Mean)
Allocation of Named Consultant for TAVI patients (% compliance)	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 Welsh Government target.

NOTES FOR JUNE DATA:

NB: In light of COVID-19, TAVI activity was suspended from 04/04/2020 and recommenced on 20/05/2020

Detail on in-hospital death: One in-hospital death 7 days post-TAVI. Cause of death - pneumonia. IR1 submitted and timeline compete. Investigation ongoing with further meeting scheduled. Completed incident investigation to be discussed at next monthly audit meeting.

Detail on >36 week patients: In light of risks associated with cardiac surgery and COVID-19, increasing numbers of patients referred to Valve Disease MDT for consideration of TAVI as alternative treatment. These patients can be approaching 36 weeks at time of referral and require TAVI work up prior to procedure. All 5 patients waiting >36 weeks for TAVI at end of June had been transferred from the cardiac surgery waiting list.