Meeting Date	**26 March 2020**	**Agenda Item**	**2.1**
Report Title	Transcutaneous Aortic Valve Insertion (TAVI)		
Report Author	Irfon Rees, Chief of Staff		
Report Sponsor	Richard Evans, Medical Director		
Presented by	Richard Evans, Medical Director		
Freedom of Information	Open		
Purpose of the Report	To update the Board on the findings of an external review of patients who died while on the waiting list for a TAVI (Transcatheter Aortic Valve Insertion); and on the actions taken since the waiting list issues came to light.		
Key Issues	• Background to ABMU Health Board (as was) commissioning an external review • Actions taken to minimise risks identified at the time • Supporting the families affected • Findings and recommendations of the review • Improvement actions • Current waiting times		
Specific Action Required ***(please choose one only)***	**Information**	**Discussion**	**Assurance**	**Approval**
	☒	☐	☐	☐
Recommendations	Members are asked to: • To **receive and note** the report; • To **note** that the Health Board has accepted the recommendations in full and actions taken to address the recommendations • To **agree** that the Quality and Safety Committee will continue to monitor the delivery of the actions on behalf of the Board; • To **agree** an update report in 6 months		

1. INTRODUCTION

This report sets out the detail of a Health Board commissioned, external review of the clinical management of patients who passed away while waiting for a cardiac procedure. The review was commissioned in response to a historic build-up of a backlog of cases, which has since been cleared. The review identified a number of deficiencies and made a number of recommendations. This report also details the Health Board's progress in implementing the recommendations.

2. BACKGROUND

Trans-catheter Aortic Valve Implantation (TAVI) is a specialist procedure offered by the health board to some elderly cardiac patients suffering from severe aortic stenosis. Aortic valve stenosis is a common disease of the older patient. The aortic valve gradually narrows without causing symptoms, but when the valve is sufficiently obstructed to cause exertional shortness of breath or chest pain, then prompt treatment is very important. Traditionally, this has been with open heart surgery, whereby the diseased valve is removed and replaced with a new artificial valve and this procedure is performed by a cardiothoracic surgeon. It remains a widely practiced operation. Unfortunately, a proportion of patients are unable to have this treatment due to age, frailty, comorbid conditions or a combination of these.

More recently an alternative treatment has become available, which involves the placement of a valve through the arterial system (usually the femoral artery) under X-ray guidance – a TAVI. This procedure is much less invasive and has become an option for patients who would otherwise not be fit for traditional aortic valve replacement surgery. Although still a major intervention for frail elderly people, TAVI is nevertheless a safer alternative than full surgery for this group of patients.

Evidence suggests that approximately half of patients with untreated severe aortic steonosis will die within one to two years. In patients who do undergo a TAVI procedure, the mortality at one year is still 30%. This demonstrates both that early intervention is important and that intervention is not always successful.

Morriston Hospital has been undertaking TAVI procedures since 2009. The service is commissioned by the Welsh Health Specialised Services Committee (WHSCC). The University Hospital of Wales is the only other provider of a TAVI services in Wales.

The demand for TAVI procedures has grown over time. In 2017-18, concerns emerged over a growing backlog of patients waiting for the procedure, and over the welfare of patients awaiting TAVI. This prompted ABMU Health Board to commission an internal review of patients who had died whilst on the waiting list.

3. CASENOTE REVIEW

Prompted by the internal review, in December 2018 the Health Board Executive Team considered it appropriate to commission an external, independent and expert review of the management of patients who had been listed, or considered for a cardiology TAVI procedure between January 2015 and November 2018 but who sadly passed away before a TAVI was undertaken. The Executive Medical Director commissioned

the Royal College of Physicians (RCP) to undertake that review, which took the form of a clinical record review of the management of 32 patients.

The review team was asked to make an assessment of the overall quality of care, given consideration to a range of factors such as patient selection, appropriateness and implementation of treatment plans, communication, record keeping, and arrangements for monitoring patients while waiting for treatment. In reviewing the overall care, it was asked to take into account whether this it was in line with national good practice and guidelines at the time of clinical contact. The review team was also asked to take a view on the probability of whether earlier intervention could have impacted on the patient's outcome and if so whether there had been a breach in the duty of care to the patient.

As well as considering the clinical management of individual patients, the RCP was asked to highlight any cross-cutting concerns and any lessons to be learned and if required, recommend appropriate actions.

The RCP provided the Health Board with its findings and recommendations in light of their review in late December 2019.

4. ACTIONS TAKEN TO MINIMISE RISKS IDENTIFIED AT THE TIME

Alongside commissioning the casenote review, the Health Board concurrently undertook urgent improvement actions to the TAVI pathway. The Board has been kept apprised of the progress of those actions. In summary:

- Immediate improvements were made to streamline the referral process and clinical pathway. A common electronic referral route and Referral to Treatment monitoring arrangements for TAVI were established. There was a reiteration of WHSSC commissioning criteria and a validation of all patients referred or recommended for TAVI to ensure they met WHSSC criteria and that they were not suitable for medical therapy of conventional aortic valve replacement.

- The Health Board invested more than £1million in additional capacity to speed up access for patients deemed suitable for TAVI. This included increasing the availability of the catheter laboratory sessions for TAVI patients, allowing for additional patients to be treated; appointment of additional nurses to support extra TAVI clinics; and additional contact with patient for triage and post procedure support. This investment allowed the backlog of cases to be cleared in early 2019. .

- The service is commissioned to deliver a 36 week pathway. There are currently 51 patients on the waiting list. Only one is waiting over 26 weeks and the majority (36 patients) have been waiting 10 weeks or under.

5. BOARD OVERSIGHT

The Board and its Quality and Safety Committee have received regular updates on the issues related to the review, in particular the progress in reducing the waiting list and making the necessary broader improvements to the pathway.

6. SUPPORTING THE FAMILIES AFFECTED

A core objective when commissioning the review was to be open and transparent with the families of those affected and to communicate and engage, where possible, with family members sensitively and in a way that allowed opportunities for feedback and comment.

The RCP has now provided detailed commentary on the clinical management of individuals reviewed. The next of kin of deceased patients whose care was reviewed by the RCP have been contacted and given the opportunity to discuss the circumstances and raise any issues. The full feedback will be shared with relevant families, who have been written to and invited to discuss the feedback with senior clinicians.

7. FINDINGS AND RECOMMENDATIONS OF THE REVIEW

Overall, the clinical reviewers found:

- Care in 23 of the 32 cases was unsatisfactory
- One case was judged to be 'room for improvement' for clinical reasons
- Two cases were deemed 'room for improvement' for organisational reasons;
- Four cases were deemed 'room for improvement' for both organisational and clinical reasons;
- One case was considered to represent good practice;
- For one case there was insufficient information available to reach a judgment.

For 23 out of the 32 cases, the reviewers concluded that, on the balance of probability, earlier intervention could have had an impact on the patient's outcome and that there had been a breach in the duty of care to the patient.

<u>Key findings</u>

The RCP provided feedback on overarching themes, as follows:

- <u>Patient selection</u> was generally thought to be appropriate. The reviewers considered that the patient was appropriately selected for a TAVI in the majority of cases. This usually meant that the patient's general condition suggested a high likelihood of benefit from having a TAVI and that investigations suggested the patient was technically suitable for TAVI. For five of the 32 cases, the question of whether the patient was appropriately selected for a TAVI was not applicable, either because the patient was not actually selected for TAVI (i.e. there was no work-up for TAVI or TAVI was never confirmed as suitable for the patient) or because the patient did not agree to the process. However, in four of the 32 cases, the reviewers found

that the patient had been inappropriately selected for a TAVI, for instance because a patient's comorbidities or condition made them a "marginal" case for TAVI.

- The reviewers found deficiencies in relation to the appropriateness of treatment plans, leading them to conclude that in most cases patients had not been managed in line with current and best practice guidance. The deficiencies were as follows:
    - Lack of clarity in the casenotes as to whether a patient had actually been listed for TAVI
    - Lack of evidence of care coordination across the cases
    - Lack of a lead clinician documented in some instances, resulting in some patients being transferred between cardiologists, or between cardiologists and surgeons
    - Lack of clarity on mechanisms for inpatient referral to Morriston hospital
    - Delays between referral and initial assessment, or between initial assessment and treatment
- The reviewers also found deficiencies in relation to the implementation and timeliness of treatment plans caused by delayed decision making, arising out of investigations being carried out in sequence rather than in parallel or delays between investigations and decision making points.
- The reviewers reported a lack of effective Multi-Disciplinary Team (MDT) working and communication. In some cases there was a lack of evidence of appropriate MDT discussion taking place; in others a lack of documentary records of MDT discussions held; and in others MDT discussions were not held in a timely way or with sufficient urgency. Most cases reviewed were rated 'poor' or 'very poor' care in relation to communication between colleagues. Similarly, the reviewers found deficits in communication with some patients and their families.
- In 12 of the 32 cases, reviewers rated 'poor' of 'very poor' the quality of clinical record keeping, often reflecting the absence of documentation relating to MDT noted above.
- The reviewers reported little documented evidence of clinical prioritisation of patients**.** They could not find evidence of a mechanism for reviewing patients awaiting TAVI treatment.

Recommendations

The reviewers concluded that the pathway needed to be streamlined; stressed the need for better coordination and clinical ownership of cases; and for more visible leadership of the service. The review team made a number of specific recommendations, given each an expected timeframe for completion of implementation. The Health Board has accepted the recommendations in their totality. The action plan attached at Annex 1 is framed around each of the specific recommendations, as made by the RCP.

8. IMPROVEMENT ACTIONS AND THE CURRENT SERVICE

As noted under section 4, above, when the RCP case note review was commissioned the Health Board concurrently instigated a number of immediate improvement actions to streamline the pathway, invested in additional capacity, and took steps to improve the co-ordination of TAVI patient care. The backlog of patients awaiting a TAVI procedure was cleared.

As noted above, the Health Board accepts the RCP's recommendations in full. A number of the Health Board's early actions were consistent with the subsequent recommendations made by the RCP. Other recommendations began to be implemented as soon as the final RCP report was received.

The RCP's review focused on a set of cases whereby patients died before receiving a TAVI procedure. It was not commissioned as a result of any concerns arising out of how TAVI procedures were performed.

It is legitimate that stakeholders nevertheless ask whether the service is safe, notwithstanding the improvements made in accessing it. The service produces a monthly Quality and Safety Dashboard for TAVI which includes a range of metrics. A snapshot of this dashboard is provided below, providing assurance against a range of metrics:

Percutaneous TAVI Outcomes for 85 TAVI cases from June 2019 to February 2020:

Outcome	**MORRISTON**	**British Cardiovascular Intervention Society-UK TAVI audit 2017**
Inpatient Mortality	1 (1.17%)	2%
30 day mortality	2 (2.35%)	Not recorded
Permanent pacemaker implantation	12.9%	8% to 16% depending on type of valve used
Major Vascular complications (VARC 2)	0 (0%)	2.3%
BARC Type 3 or worse bleeding	0 (0%)	Not recorded
Bail out Valve in Valve	1 (1.17%)	1.1%
Length of stay post procedure (median)	2 days	3 days

[Medical terms/acronyms to be explained in footnotes]

9. FURTHER WORK WITH THE ROYAL COLLEGE OF PHYSICIANS

Given the significance of the RCPs conclusions in its case note review, the Health Board considers it crucial that a case note review also be undertaken on all other patients who died while listed for a TAVI procedure and that these be subject to the same level of external scrutiny. This includes all other cases considered by the internal review but not initially considered by the RCP; and any other cases prior to 2015 or after 2018. The number of cases is 46 in total. The RCP has been commissioned to review these cases. The next of kin/families of those patients have been written to, and invited to discuss the care of their loved one with senior Health Board staff. The outcome of the RCP's review of specific cases will be shared with the relevant next of kin as and when it becomes available.

An expert panel convened by the RCP was also invited to undertake a site review to provide assurance regarding the improvement work and to advise on any further service changes required. The review team visited the Health Board for two days on 22-23 July 2019 and a final report is expected soon. The Board will be kept apprised of the ongoing improvement work.

10. CONCLUSION

In a statement being issued on the day of the Board meeting, the Health Board apologises unreservedly to patients and their families who were affected by past delays in accessing the TAVI procedure and, the harm this caused. These apologies are also being communicated directly to the families involved.

The report outlines immediate actions taken to reduce the waiting list before receiving the findings of the review, and the Health Board has acted promptly on the advice and recommendations following the review. Improvements to the way the TAVI service in now managed means we are treating TAVI patients much more quickly and effectively. The Health Board remains steadfastly committed to ensuring the service is operating to the highest standards. Progress against any ongoing improvement actions will be scrutinised by the Quality and Safety Committee and the outputs from the RCP's site visit will be used to provide both further learning and assurance.

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	January 2020 **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	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**			

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	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**			
	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 Intervention 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	June 2020			
	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

<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	July 2019 **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.	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**

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	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	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.	February 2020	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		February 2020			
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.	February 2020			
Patient to be assigned responsible consultant for overseeing care		February 2020			
Documentation of MDT discussion and decision		February 2020			
Communication of MDT discussion and decision **with patient**		February 2020			
Documentation of MDT discussion and decision **with referring clinician and GP**		February 2020			

<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.	February 2020	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)		February 2020			
Communication to patients: Confirm process for review		February 2020			
Communication to patients: Confirm process for escalation		February 2020			
Communication to referring clinician: Confirm date/time of their MDT discussion (see R6)		February 2020			
Communication to referring clinician: Confirm outcome of MDT discussion (see R6)		February 2020			
Communication to referring clinician: Confirm process for review		February 2020			
Communication to referring clinician: Confirm process for escalation		February 2020			
Documentation in clinical record to reflect communication to patient and referring clinician - as described above		February 2020			

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	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	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		June 2020			
Formal appointment of Clinical Lead for TAVI		June 2020			

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

<u>Recommendation 11.</u> 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

<u>Recommendation 12.</u> 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	November 2018 **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	March 2020			
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			

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			

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)		June 2020
All Health Boards whose patients were involved in this review have been informed of the review's findings and the actions being taken		June 2020

Additional Actions	Assurance Group	Updated timescales for completion

DYDDIAD: 26 Mawrth 2020

Datganiad ynghylch Mewnblannu Falf Aortig Trawsgathetr (TAVI)

Nodir papur a gyhoeddwyd yng nghyfarfod Bwrdd Iechyd Prifysgol Bae Abertawe heddiw, 26 Mawrth 2020, canfyddiadau Coleg Brenhinol y Meddygon i'r ffordd y rheolwyd rhai cleifion wrth iddynt aros am lawdriniaeth gardiaidd arbenigol.

Mae Mewnblannu Falf Aortig Trawsgathetr, neu TAVI, yn llawdriniaeth twll clo a gynigir gan y Bwrdd Iechyd i rai cleifion cardiaidd oedrannus, yn arbennig i'r rhai dros 80 oed sydd yn rhy fregus i dderbyn llawdriniaeth calon agored draddodiadol. Mae llawdriniaeth TAVI yn trin y falf aortig sydd yn culhau, ac er y bydd yn dal i ymyrryd ar bobl fregus oedrannus, mae'n ddewis diogelach na llawdriniaeth gyfan i'r grŵp cleifion.

Fodd bynnag, codwyd pryderon ychydig gan feddygon cardiaidd am faint o amser yr oedd rhai cleifion yn aros am lawdriniaeth TAVI, ac yn drist, bu farw rhai cleifion cyn iddynt dderbyn y llawdriniaeth.

Wrth adolygu'r pryderon hyn, cymerwyd sawl cam brys gan y Bwrdd Iechyd i wella rheolaeth y gwasanaeth, a hefyd comisiynwyd Coleg Brenhinol y Meddygon gan y Bwrdd Iechyd i weithio gyda ni.

Gofynnom i'r Coleg Brenhinol adolygu 32 achos rhwng 2015 a 2018 lle na dderbyniodd cleifion eu llawdriniaeth TAVI cyn iddynt farw, a daethpwyd i'r casgliad y gallai ymyrraeth gynharach fod wedi cael effaith ar ganlyniad y claf mewn 23 o'r achosion hyn.

Rydym yn hynod ddiolchgar i'r Coleg Brenhinol am eu hargymhellion. Cyflawnwyd y rhan fwyaf o'r camau hyn gennym yn barod, wedi i ni ddechrau ar wella brys i reolaeth y gwasanaeth cyn cysylltu â'r Coleg Brenhinol hyd yn oed. Mae amseroedd aros bellach wedi gwella. Caiff manylion ar bob cam a gymerwyd eu cynnwys yn y papur Bwrdd.

Dywedodd Prif Weithredwr Bwrdd Iechyd Prifysgol Bae Abertawe, Tracy Myhill:

"Ymddiheurwn yn ddiffuant i gleifion a'u teuluoedd a gafodd eu heffeithio gan oedi wrth geisio derbyn llawdriniaeth twll clo ar falf y galon, sef TAVI, a'r niwed mae wedi'i achosi.

“Mae amseroedd aros am lawdriniaeth TAVI ar gyfer rhai o’r cleifion cardiaidd wedi bod yn rhy hir, a chyda gofid y cydnabyddwn y bu farw rhai cleifion cyn i ni allu cynnig y llawdriniaeth iddynt.”

Dywedodd Cyfarwyddwr Meddygol Bwrdd Iechyd Prifysgol Bae Abertawe, Dr Richard Evans:

“Gallwn sicrhau y cymerom gamau yn syth er mwyn lleihau’r rhestr aros cyn gofyn i Goleg Brenhinol y Meddygon weithio gyda ni. Gwnaethon ni ymgymryd â’r cyngor a roddwyd ganddynt, a gosodwyd ystod eang o weithdrefnau.

“Mae gwelliannau yn y ffordd mae’r gwasanaeth TAVI yn cael ei reoli yn golygu ein bod yn trin cleifion TAVI yn gyflymach.”

Un o’r prif gamau oedd penodi cydlynydd TAVI pwrpasol i oruchwylio’r gwasanaeth. Mae’r rôl wedi bod ar waith am gyfnod, ac yn sicrhau y caiff gofal cleifion ei fonitro drwy’r amser wrth iddynt aros am driniaeth.

Hefyd, rydym ni wedi buddsoddi mwy na £1 filiwn o gapasiti ychwanegol i gyflymu mynediad i gleifion sydd yn addas ar gyfer TAVI. Rydym ni wedi cynyddu argaeledd sesiynau labordy cathetr i gleifion TAVI, sydd wedi ein galluogi i drin mwy o gleifion.

Daeth nyrsys ychwanegol i mewn i gefnogi clinigau TAVI ychwanegol, cysylltiadau dros y ffôn â chleifion a chynnig cefnogaeth frysbennu ac ôl-lawdriniaeth.

Fel dewis arall i lawdriniaeth calon agored, mae’r galw am lawdriniaeth TAVI yn cynyddu, ac mae disgwyl iddo gynyddu o ganlyniad i'r boblogaeth oedrannus. Ar yr un pryd, mae galw mawr am gymorth ac ymyrraeth arbenigol eraill ar gyfer problemau ar y galon. Roedd hyn yn ychwanegu at yr amser oedd yn cymryd i asesu cleifion TAVI posibl.

Rydym bellach wedi gweithio’n agos gyda chomisiynwyr ac wedi cytuno ar raglen flaen o o leiaf 100 llawdriniaeth TAVI y flwyddyn, y mae disgwyl i hyn fodloni rhagalw’r dyfodol a lleihau’r risg o gael rhestrau aros hir eto.

Camau nesaf

Er mwyn sicrhau bod yr adolygiad mor drylwyr â phosibl, rydym bellach wedi gofyn i'r Coleg Brenhinol edrych ar achosion eraill lle na dderbyniodd cleifion eu llawdriniaeth TAVI. Mae hyn yn cwmpasu’r holl amser y mae llawdriniaeth TAVI wedi cael ei chynnig gan y Bwrdd Iechyd (ers 2009) yn ei chyfanrwydd.

Mae panel arbenigol o Goleg Brenhinol y Meddygon hefyd wedi ymgymryd ag adolygiad safle er mwyn asesu’r gwelliannau a chynghori ar unrhyw newidiadau gwasanaeth sydd eu hangen.

Rydym wedi bod yn cysylltu â theuluoedd a gofalwyr cleifion sydd yn ymwneud â’r adolygiad hwn er mwyn cael hyd i adborth, rhannu manylion yr adroddiad (a manylion eu hachosion unigol), cynnig cyfarfodydd a chefnogaeth, ac unrhyw wybodaeth bellach sydd angen arnynt.

Mae llinell gymorth ar gael i deuluoedd sydd wedi cysylltu'n uniongyrchol a chafodd manylion y llinell gymorth eu hanfon atynt.

Nodiadau i Olygyddion:

Mae stenosis aortig yn gyflwr difrifol iawn, a all effeithio ar bobl o bob oedran, ond yn effeithio ar bobl oedrannus y fwyaf. Mae'n digwydd pan fydd falf aortig y galon yn culhau, sydd yn atal gwaed rhag llifo o'r galon ac o gwmpas y corff.

Gan amlaf, mae'n gyflwr nas canfyddir, heb symptomau amlwg. Erbyn i symptomau gael eu profi, byddai wedi cyrraedd gradd ddifrifol iawn. Mae yna risg fawr o fethiant y galon neu anawsterau eraill.

Nid oes ymyrraeth feddygol i wrthdroi neu atal cynnydd y cyflwr, ac ymhen amser gall y claf angen i'r falf gael ei hamnewid. Yr opsiwn gorau i gleifion iau a ffit yw llawdriniaeth calon agored fel arfer i amnewid y falf aortig. Fodd bynnag, nid yw nifer o bobl hŷn, y gall eu hiechyd gael ei effeithio arno gan gyflyrau eraill, yn ddigon ffit i dderbyn llawdriniaeth fawr fel hon.

Mae Mewnblannu Falf Aortig Trawsgathetr (TAVI) ar gael i rai o'r cleifion hyn nad yw'n ddigon ffit i dderbyn llawdriniaeth fawr. Nid yw'r llawdriniaeth yn cynnwys llawdriniaeth calon agored, a gall y falf gael ei hamnewid drwy endoriad bach yn y croen (twll clo).

Nid yw llawdriniaeth TAVI yn addas i bob claf, ac mae yna risgiau, yn enwedig i'r rhai sydd â phroblemau iechyd sylweddol neu eiddilwch. I'r rhai hyn, yr opsiwn gorau iddynt fydd triniaeth â meddyginiaethau i reoli eu symptomau a'u helpu i fyw bywyd cyfforddus.

Ysbyty Treforys oedd yr ysbyty cyntaf yng Nghymru i'w chynnig yn 2009, ac mae ar gael yng Nghymru yn Ysbyty Treforys ac Ysbyty Athrofaol Cymru Caerdydd yn unig.

Final draft

DATE: 26th March 2020

Statement re Trans-catheter Aortic Valve Implantation (TAVI)

A paper published at a meeting of the Swansea Bay University Health Board today, 26th March 2020, details findings by the Royal College of Physicians into the way some patients were managed while they were waiting for a specialist cardiac procedure.

Called Trans-catheter Aortic Valve Implantation, or TAVI; it is a keyhole procedure offered by the health board to some elderly cardiac patients, particularly over the age of 80, who are too frail to undergo traditional open-heart surgery. TAVI treats the narrowing of the aortic valve, and although still a major intervention for frail elderly people, it is nevertheless a safer alternative than full surgery for this group of patients.

However, concerns were rightly raised by cardiac doctors about the length of time some patients were waiting for TAVI, as some very sadly passed away before receiving the procedure.

Following these concerns, the health board took a number of urgent actions to improve the management of the service and also commissioned the Royal College of Physicians to assist us.

We asked the Royal College to review 32 cases between 2015 and 2018 where patients did not receive their TAVI treatment before they passed away, and it concluded that earlier intervention could have had an impact on the patient's outcome in 23 of these cases.

We are grateful to the Royal College for their recommendations. The majority of these actions are already completed, as we began urgent improvements to the management of the service before even contacting the Royal College. Waiting times are now much improved. Included in the Board paper is the detail of all the actions taken.

Swansea Bay UHB Chief Executive, Tracy Myhill, said:

"We apologise unreservedly to patients and their families affected by past delays in accessing the keyhole heart valve procedure known as TAVI, and the harm this has caused.

“Waiting times for TAVI for some of our cardiac patients have been too long, and it is with profound regret that we acknowledge some patients passed away before we were in a position to offer them the procedure.”

Swansea Bay UHB Medical Director, Dr Richard Evans, said:

“We can give assurances that we took immediate actions to reduce the waiting list before inviting the Royal College of Physicians to assist us. We acted promptly on the advice given by them, and a range of robust actions are already in place.

“Improvements to the way the TAVI service is managed means we are now treating new TAVI patients much more quickly.”

One of the immediate and key actions included appointing a dedicated TAVI coordinator to oversee the service. This role has been fully operational for some time, and is ensuring that patients’ care is continually monitored at all times while they wait for treatment.

We have also invested more than £1million in additional capacity to speed up access for patients deemed suitable for TAVI. We have increased the availability of the catheter laboratory sessions for TAVI patients, which has allowed us to treat more patients.

Additional nurses have also been brought in to support extra TAVI clinics, telephone contact with patients and offer both triage and post procedure support.

As an alternative to open heart surgery, demand for TAVI is growing, and is expected to continue growing as a result of an ageing population. At the same time, there has been increased demand for other specialist support and interventions for heart problems. This was adding to the time taken to assess potential TAVI patients.

We have now worked closely with commissioners and agreed a forward programme of at least 100 TAVI procedures annually, which is expected to meet future forecast demand and reduce the risk of long waiting lists building again.

Next steps

To ensure the review is as thorough as possible, we have now asked the Royal College to look at other cases where patients did not receive their TAVI treatment. This covers the entire period of time TAVI has been offered by the health board (since 2009) for completeness.

An expert panel from the Royal College of Physicians has also undertaken a site review to assess the improvements and advise on any other service changes required.

We have been contacting the families and carers of patients involved in this review to gather feedback, share details of the report (and details of their individual cases), offer meetings and support, and any further information they might need.

A helpline is available for families we have contacted directly and the details of the helpline have been forwarded to them.

Notes to Editors:

Aortic stenosis is a very serious condition, which can affect people of all ages, but is commonest in elderly people. It occurs when the heart's aortic valve narrows, obstructing blood flow out of the heart and around the body.

Often it can be undetected, with no obvious symptoms. By the time symptoms are experienced, it has usually reached a severe stage. This carries a significant risk of heart failure and other complications.

There is no medical intervention to reverse or halt the progression of the condition and eventually patients may need the valve replaced. In younger and fitter patients, the best option is usually open heart surgery to replace the aortic valve. However, many older people, whose health may be affected by other conditions, are not fit to have such major surgery.

Trans-catheter Aortic Valve Implantation (TAVI) is available for some of these patients who are not fit for major surgery. This procedure does not involve open heart surgery and the valve can be replaced through a small incision in the skin (keyhole).

TAVI is not suitable for all patients and is not without risk, especially for those with significant health issues or frailty. For these people, treatment with medicines to manage their symptoms and help them lead a comfortable life is the best option.

Morriston Hospital was the first centre in Wales to offer it in 2009, and it is only available in Wales in Morriston and UHW Cardiff.

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