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|   |  |                   |                    |                 |
|---|--|-------------------|--------------------|-----------------|
| <b>Meeting/Date</b>   | <b>24 September 2020</b>   |                   | <b>Agenda Item</b> | <b>2.4</b>      |
| <b>Report Title</b>   | Transcatheter aortic valve insertion (TAVI) – Update   |                   |                    |                 |
| <b>Report Author</b>  | Dr Richard Evans, Executive Medical Director   |                   |                    |                 |
| <b>Report Sponsor</b>   | Dr Richard Evans, Executive Medical Director   |                   |                    |                 |
| <b>Presented by</b>   | Dr Richard Evans, Executive Medical Director   |                   |                    |                 |
| <b>Freedom of Information</b>                                 | Open   |                   |                    |                 |
| <b>Purpose of the Report</b>                                  | To update the Health Board on the current position in relation the progress made in treating the patients on the TAVI waiting list and the Royal College of Physicians' (RCP) review of the service.   |                   |                    |                 |
| <b>Key Issues</b>   | <ul style="list-style-type: none"> <li>The Royal College of Physicians' (RCP) report on the review of casenotes of 32 patients who died while on the waiting list for TAVI has been received and an action plan has been developed.</li> <li>This paper provides assurance regarding the actions taken to demonstrate improvement in the governance of the service.</li> <li>A detailed communications plan has been developed to share the report's findings with patients' families/next of kin and key stakeholders.</li> </ul> |                   |                    |                 |
| <b>Specific Action Required</b><br><i>(please ✓ one only)</i> | <b>Information</b>   | <b>Discussion</b> | <b>Assurance</b>   | <b>Approval</b> |
|   |  |                   | ✓                  |                 |
| <b>Recommendations</b>  | Members are asked to: <ul style="list-style-type: none"> <li><b>NOTE</b> the update provided</li> </ul>  |                   |                    |                 |

# TRANSCUTANEOUS AORTIC VALVE INSERTION UPDATE

## 1. INTRODUCTION

This paper provides an update on progress on transcatheter 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 has now occurred

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

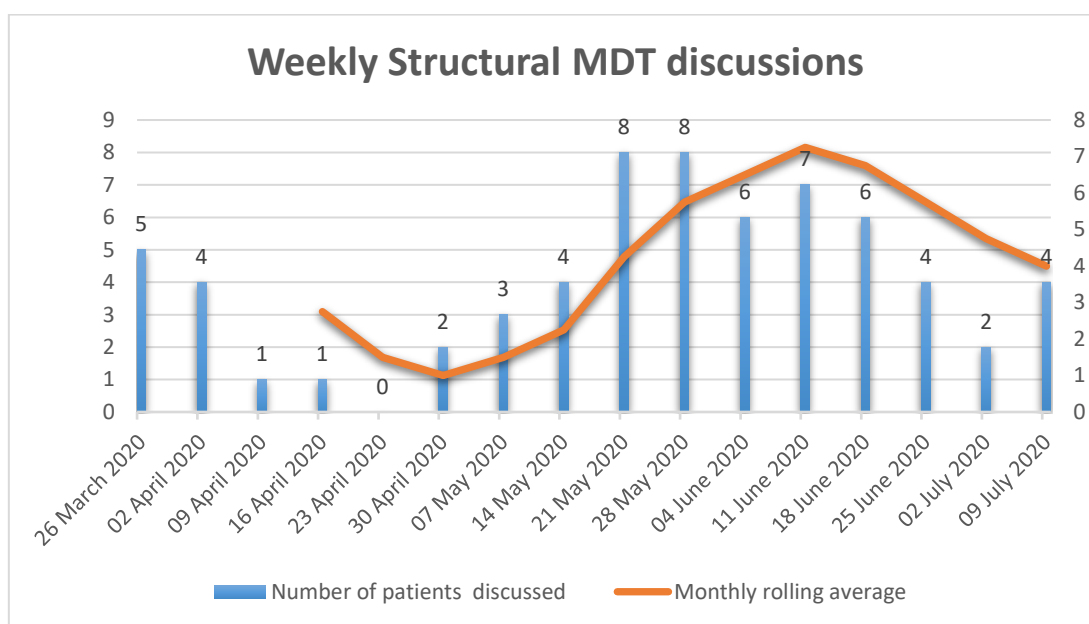
Since late March 2020, the joint clinic has been suspended due to the COVID-19 pandemic. The Structural Heart Multidisciplinary Team (MDT) has continued on a weekly basis with both Cardiology and Cardiac Surgery representation (including Clinical Nurse Specialist). All patients referred for surgical 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 26<sup>th</sup> 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<br>(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-of-area 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 19<sup>th</sup> 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 25<sup>th</sup> March due to COVID and recently recommenced. The current list position is as follows:

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

Of the patients waiting >26 weeks, one patient has an admission date for procedure within the next 5 days; the other patient is on hold due to patient choice while they decide whether they want to go ahead with the procedure.

The department is currently running additional TAVI lists to catch up with the backlog of cases due to COVID-19.

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.

## **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 spend against a revised budget of £1.7m is a planned spend of £1.4m. Current commitments against this spend total £1.1m. At present the forecast is that spend will fall below the £1.7m

budget as no work has been allocated to POWH and the anticipated patient transportation expenses have not arisen.

A costed plan to maintain the current service from April 2019-March 2020 in anticipation of securing WHSSC for a sustainable TAVI service going forward being in place by April 2020 has been agreed. WHSSC has confirmed that funding will be available for the TAVI service from April 2020 onwards.

## **8. RECOMMENDATION**

Members are asked to:

- **NOTE** the update provided

| Governance and Assurance  |  |   |  |  |  |  |  |                 |   |  |  |
|---|--|---|--|--|--|--|--|-----------------|---|--|--|
| Link to corporate objectives<br>(please ✓)  | Promoting and enabling healthier communities |   | Delivering excellent patient outcomes, experience and access |  | Demonstrating value and sustainability |  | Securing a fully engaged skilled workforce |                 | Embedding effective governance and partnerships |  |  |
|   |  |   | ✓  |  |  |  | ✓  |                 | ✓   |  |  |
| Link to Health and Care Standards<br>(please ✓)   | 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 TAVI deaths so that lessons can be learned to drive improvement in quality, safety and patient experience.  |  |   |  |  |  |  |  |                 |   |  |  |
| Financial Implications  |  |   |  |  |  |  |  |                 |   |  |  |
| At present the forecast is that spend will fall below the £1.7m budgeted  |  |   |  |  |  |  |  |                 |   |  |  |
| 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 - <a href="https://futuregenerations.wales/about-us/future-generations-act/">https://futuregenerations.wales/about-us/future-generations-act/</a> )                         |  |   |  |  |  |  |  |                 |   |  |  |
|   |  |   |  |  |  |  |  |                 |   |  |  |
| Report History  |  |   |  |  |  |  |  |                 |   |  |  |
| Appendices  |  | Appendix 1: TAVI Assurance Framework, September 2020<br>Appendix 2: TAVI Quality Dashboard, August 2020 |  |  |  |  |  |                 |   |  |  |



## Appendix 1

Updated September 2020

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

|   |  |
|---|--|
| <b>Recommendation 1.</b> 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<br><b>Completed</b>   |                    |                 |                                   |
|   | 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<br><b>Completed</b>   |                    |                 |                                   |
|   | 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<br><b>Completed</b>   |                    |                 |                                   |
| 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<br><b>Completed</b> |                    |                 |                                   |

**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: Service Director, Morriston Hospital

| Key actions taken to meet the requirements of the recommendation   | Evidence to support action completion   | Completion timescale             |
|--|---|----------------------------------|
| 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<br><b>Completed</b>  |
|  | Clear the waiting list of patients who are overdue for TAVI procedure   | March 2019<br><b>Completed</b>   |
|  | Undertake a demand/capacity analysis to ensure deliverability of current service within commissioned timescales   | March 2019<br><b>Completed</b>   |
| 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<br><b>Completed</b> |
| 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  | <b>Completed</b>                 |
|  | Review the commissioning arrangements with WHSC to align with BCIS standards and component waiting times  | June 2020                        |

| Additional Actions   | Assurance Group  | Updated timescales for completion |
|--|--|-----------------------------------|
| Monthly report of component waiting times for TAVI   | Quality and Safety Committee   | Monthly for minimum 12 months     |
| None   | None   | None                              |
| Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales | WHSC commissioning meeting with Health Board; reported to Quality and Safety Committee | July 2020                         |
| Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales | WHSC commissioning meeting with Health Board; reported to Quality and Safety Committee | July 2020                         |
| None   | None   | None                              |
| Review TAVI pathway with commissioners to ensure that the service is commissioned to deliver within best practice timescales | WHSC 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            |
|--|---|---------------------------------|
| Review process for receiving and processing referrals                          | A single common electronic referral route for TAVI has been established | August 2018<br><b>Completed</b> |
| Ensure that pathway design enables compliance with WHSC commissioning criteria | Pathway conforms to WHSC commissioning criteria                         | August 2018<br><b>Completed</b> |
| Implement system of pooled referrals   | Pooled referral system implemented                                      | August 2018<br><b>Completed</b> |

| Additional Actions                      | Assurance Group              | Updated timescales for completion |
|---|------------------------------|-----------------------------------|
|   |                              |                                   |
|   |                              |                                   |
| 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             |
|--|---|----------------------------------|
| 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<br><b>Completed</b>    |
| Circulate process and contact details to referring clinicians across the network and partner organisations (WAST, Hywel Dda University Health Board) | Communication with all referring clinicians distributed.                | July 2019<br><b>Completed</b>    |
| 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<br><b>Completed</b> |

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

**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          |
|---|---|-------------------------------|
| Establish joint clinic with Cardiology and Cardiothoracic Surgery | Joint clinic established, involving Cardiologist and Cardiothoracic surgeon - commenced July 2019 | July 2019<br><b>Completed</b> |

| Additional Actions            | Assurance Group              | Updated timescales for completion |
|-------------------------------|------------------------------|-----------------------------------|
| 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           |
|--|---|--------------------------------|
| Implement stand-alone MDT meeting held separately to TAVI Joint Clinic   | Weekly standalone MDT meeting commencing February 2020.   | March 2020<br><b>Completed</b> |
| Frequency of the MDT to reflects the need to make prompt decisions; membership of MDT has appropriate multidisciplinary representation |   | March 2020<br><b>Completed</b> |
| 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. | March 2020<br><b>Completed</b> |
| Patient to be assigned responsible consultant for overseeing care  |   | March 2020<br><b>Completed</b> |
| Documentation of MDT discussion and decision   |   | March 2020<br><b>Completed</b> |
| Communication of MDT discussion and decision <b>with patient</b>   |   | March 2020<br><b>Completed</b> |
| Documentation of MDT discussion and decision <b>with referring clinician and GP</b>  |   | March 2020<br><b>Completed</b> |

| 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   |
|  |                              |                                   |
|  |                              |                                   |
|  |                              |                                   |
|  |                              |                                   |
|  |                              |                                   |

**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 |
|---|---|--------------------------------|--|------------------------------|-----------------------------------|
| <b>Communication to patients:</b> 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. | March 2020<br><b>Completed</b> | Audit of communications with patients/GPs/referrers to ensure system is robust | Quality and Safety Committee | Quarterly for minimum 12 months   |
| <b>Communication to patients:</b> Confirm outcome of MDT discussion (see R6)                                      |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to patients:</b> Confirm process for review  |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to patients:</b> Confirm process for escalation  |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to referring clinician:</b> Confirm date/time of their MDT discussion (see R6)                   |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to referring clinician:</b> Confirm outcome of MDT discussion (see R6)                           |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to referring clinician:</b> Confirm process for review   |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| <b>Communication to referring clinician:</b> Confirm process for escalation                                       |   | March 2020<br><b>Completed</b> |  |                              |                                   |
| Documentation in clinical record to reflect communication to patient and referring clinician - as described above |   | March 2020<br><b>Completed</b> |  |                              |                                   |

**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           |
|--|---------------------------------------|--------------------------------|
| Appointment of TAVI Clinical Nurse Specialist (CNS)              | TAVI CNS appointed                    | November 2018 <b>Completed</b> |
| Priority within job plan to manage all patients on TAVI pathway  | Agreed within role of TAVI CNS        | August 2019 <b>Completed</b>   |
| Priority within job plan to manage all patients on TAVI pathway  | Agreed within role of TAVI CNS        | August 2019 <b>Completed</b>   |

| Additional Actions | Assurance Group | Updated timescales for completion |
|--------------------|-----------------|-----------------------------------|
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |

**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       |
|--|---------------------------------------|----------------------------|
| Appointment of Acting Clinical Director for Cardiology           | Acting CD for Cardiology appointed    | <b>Completed</b>           |
| Acting TAVI Clinical Lead appointed                              | Acting TAVI Clinical Lead appointed   | <b>Completed</b>           |
| Formal appointment of Clinical Director for Cardiology           | CD for Cardiology appointed           | June 2020 <b>Completed</b> |
| Formal appointment of Clinical Lead for TAVI                     |                                       | <b>Completed</b>           |

| Additional Actions | Assurance Group | Updated timescales for completion |
|--------------------|-----------------|-----------------------------------|
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |

**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 |
|--|--|----------------------|
| Named clinician responsible for every patient                    | Named clinician for every patient allocated by MDT. Clarity regarding responsibility of each named clinician 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) | <b>Completed</b>     |

| Additional Actions                            | Assurance Group              | Updated timescales for completion |
|---|------------------------------|-----------------------------------|
| 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 | 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 switch 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 | Additional Actions   | Assurance Group              | Updated timescales for completion |
|--|--|----------------------|--|------------------------------|-----------------------------------|
| Ensure CT is the investigation of choice rather than TOE         | 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                         |
|  | 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              |
|---|---|-----------------------------------|
| 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<br><b>Completed</b> |
| 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<br><b>Completed</b>    |
| 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<br><b>Completed</b>    |

| Additional Actions | Assurance Group | Updated timescales for completion |
|--------------------|-----------------|-----------------------------------|
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |

**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             |
|--|---|----------------------------------|
| 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  | <b>Completed</b>                 |
| 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<br><b>Completed</b> |
| A report will be presented and discussed at a formal meeting of the Health Board   |   | March 2020<br><b>Completed</b>   |

| Additional Actions  | Assurance Group              | Updated timescales for completion |
|---|------------------------------|-----------------------------------|
| 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     |
|   |                              |                                   |
|   |                              |                                   |



|   |  |
|---|--|
| <b>Recommendation 15.</b> 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<br><b>Completed</b> |
| The report has been shared with Welsh Health Specialised Services Committee (WHSSC) as commissioners                                  | Meeting with representatives of WHSSC  | March 2020<br><b>Completed</b>   |
| The report has been shared with Hywel Dda University Health Board   | Meeting with representatives of Hywel Dda UHB  | March 2020<br><b>Completed</b>   |
| The report has been formally shared with Health Inspectorate Wales (HIW)  | Report shared with HIW   | March 2020<br><b>Completed</b>   |
| 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<br><b>Completed</b>   |

| Additional Actions | Assurance Group | Updated timescales for completion |
|--------------------|-----------------|-----------------------------------|
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |
|                    |                 |                                   |

## TAVI Service Quality & Safety Dashboard

| Measure   | Benchmark <sup>1</sup> | Mar-20 | Apr-20 | May-20 | Jun-20    | Jul-20   | Aug-20  | Sep-20 | Oct-20 | Nov-20 | Dec-20 | Financial Year to date (August 2020) |
|---|------------------------|--------|--------|--------|-----------|----------|---------|--------|--------|--------|--------|--------------------------------------|
| Number of procedures completed                                  |                        | 13     | 2      | 4      | 24        | 21       | 12      |        |        |        |        | 63                                   |
| Procedural deaths (%)   | 2%                     | 0      | 0      | 0      | 0         | 0        | 25% (1) |        |        |        |        | 1.5% (1)                             |
| In-hospital deaths (%)  | 2%                     | 0      | 0      | 0      | 4.2% (1)  | 0        | 0       |        |        |        |        | 1.5% (1)                             |
| 30 day mortality (%)  | 5%                     | 0      | 0      | 0      | 0         | 0        | 0       |        |        |        |        | 0% (0)                               |
| VARC-2 Major Complications (%)                                  | 2.3%                   | 0      | 0      | 0      | 0         | 0        | 0       |        |        |        |        | 0% (0)                               |
| Stroke (%)  | 2.6%                   | 0      | 0      | 0      | 0         | 0        | 0       |        |        |        |        | 0% (0)                               |
| Pacemaker post TAVI (%)   | 12%                    | 7% (1) | 0      | 0      | 12.5% (3) | 9.5% (2) | 25% (3) |        |        |        |        | 12.7% (8)                            |
| Migration/ectopic deployment (%)                                | 1.1%                   | 0      | 0      | 0      | 0         | 0        | 0       |        |        |        |        | 0% (0)                               |
| Length of stay (days TAVI to discharge)                         | 5.5                    | 3.8    | 2      | 2      | 1.8       | 2        | 2       |        |        |        |        | 1.9 (Mean)                           |
| RTT (number of patients >36 weeks at end of month)              | 0                      | 0      | 0      | 3      | 5         | 2        | 0       |        |        |        |        | 2 (Mean)                             |
| Allocation of Named Consultant for TAVI patients (% compliance) | 100%                   | 100    | 100    | 100    | 100       | 100      | 100     |        |        |        |        | 100%                                 |

### Previous years

| 2017/18 | 2018/19 | 2019/20 |
|---------|---------|---------|
| 41      | 114     | 121     |

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.

### NOTES FOR AUGUST DATA:

#### ACTIVITY

Seasonal reduction in activity for the month of August was expected and forecast.

#### ISSUES OF NOTE

1 procedural death in August

Full report and investigation completed on Datix. Summary of investigation provided to Medical Director. No service failures identified. Case to be discussed at Cardiology M&M meeting in September.